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Comparison of the Metabolic and Perceptual Costs of Transporting Oxygen Delivery Systems by Patients with COPD

By

James Hunter Brohman ©

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science in

Experimental Medicine

Department of Medicine

Edmonton, Alberta

Fall 1994

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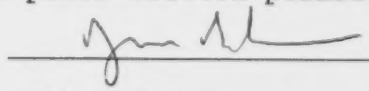

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled Comparison of the Metabolic and Perceptual Costs of Transporting Oxygen Delivery Systems by Patients with COPD submitted by James Hunter Brohman in partial fulfillment of the requirements for the degree of Master of Science in Experimental Medicine.

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ABSTRACT

BACKGROUND AND PURPOSE. The purpose of this thesis was to compare the physiologic and perceptual impact of walking with two supplemental oxygen systems (the gaseous "E" cylinder = CGOS and the liquid oxygen pack = LOS) transported by three methods (by two-wheeled cart, = LOS-2WC; by an assistant = AC; or suspended from the shoulder = LOSSH). SUBJECTS. Ten male patients with severe chronic obstructive pulmonary disease (COPD) were studied. METHODS. A pilot group of four patients preceded the main group (six patients) to examine the reproducibility of the outcome measurements (heart rate = HR; arterial oxygen saturation = SaO_2; and breathlessness = modified Borg scores) during the walking tests. They performed four corridor walking tests (CWTs) twice: one with the LOS pulled on a two-WC, one with the LOS carried from the shoulder, one with the LOS carried by an assistant, and one pulling the CGOS on a two-WC. Patients also walked on the treadmill (TM) while carrying the LOS or without the pack on two occasions while HR, oxygen uptake ($\dot{V}O_2$) carbon dioxide production ($\dot{V}CO_2$), and breathlessness were recorded. The main study group followed the same protocol as that of the pilot group with the exception

that there was no repeat testing. RESULTS. The reproducibility of the pilot patients' variables of interest was inconsistent. Overall mean HR, calculated $\dot{V}O_2$, and breathlessness scores were significantly lower during the CWTS with the AC method of oxygen transport versus (vs.) the CGOS and LOSSH methods, but not significantly different for the other methods of oxygen transport. During TM exercise while carrying the oxygen apparatus, there was a 9.7% increase in $\dot{V}O_2$ and 11.7% increase in $\dot{V}CO_2$ compared to "unloaded" walking. From the questionnaire, eight out of ten patients ranked the LOSSH mode of oxygen transport as the most energy demanding during walking followed by the CGOS. DISCUSSION AND CONCLUSIONS. The results of this thesis indicate that, in elderly males with severe COPD, there is no significant difference in the physiologic or perceptual stress of walking when pulling the CGOS vs. pulling the LOS, or when carrying the LOS on the shoulder vs. pulling the LOS on a cart. Also, there is a significant metabolic burden associated with carrying the LOS from the shoulder compared to that of walking on a treadmill without a load.

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a progressive illness that leaves patients severely disabled and breathless. Long-term oxygen (O_2) therapy (LTOT) has been shown to significantly increase survival (1,2) and to improve neuropsychological functioning (2) in hypoxemic patients with COPD. Further, supplemental oxygen has been reported to substantially reduce dyspnea (3,4) and to increase exercise endurance (3,5,6) in some patients with COPD. To achieve these benefits, oxygen therapy should be administered at least 15 hours per day (7).

Possible mechanisms for enhanced physical performance and reduced breathlessness with supplemental oxygen include (a) greater delivery of oxygen to the tissues (8), (b) decreased ventilatory muscle fatigue (9), (c) reduced oxygen cost to the respiratory muscles (10), (d) reduction in ventilation (11,12), and (e) decreased ventilatory drive (12,13).

Many of the studies on the benefit of supplemental oxygen were conducted while patients exercised on a treadmill (14-16) or on a bicycle ergometer (6,17) while breathing supplemental oxygen but not having to actually carry the oxygen apparatus. There is

conflicting evidence in the literature on whether the additional weight of carrying a portable oxygen system (either liquid or gaseous) detracts from the gains made in exercise tolerance by breathing supplemental oxygen (18,19).

Also, studies have revealed that although patients perceive supplemental oxygen as being beneficial to exercise tolerance, 40% (20) to 50% (21) of these patients were not using a portable supplemental oxygen system on a regular basis outside the home even though oxygen was prescribed 24 hours per day. The major factors that accounted for the poor compliance to portable oxygen therapy were the weight of the equipment, the negative feelings associated with the aesthetics of the devices (especially the nasal cannulae), and the short duration of the oxygen supply from the gaseous cylinder.

Unfortunately, patients with severe lung disease are least able to manage the added burden of transporting an oxygen delivery system when walking because of poor exercise tolerance. Possible mechanisms for exercise intolerance are multifactorial and may include moderate to severe impairment of lung

mechanics (22), poor gas exchange, and respiratory muscle fatigue (23). Exercise limitation may also be due to right ventricular dysfunction (24), malnutrition, and deconditioning (25).

Patients adapt to this severe disability by employing countermeasures that help conserve energy and reduce dyspnea. Some examples are the pacing of activities (26), pursed-lip breathing (23, 26), and the use of assistive devices such as wheeled carts to transport the portable oxygen system (18, 27).

Although various researchers have studied the portability of liquid and gaseous oxygen, there seems to be a lack of consensus on the magnitude of the burden that a portable oxygen system imposes on the patient during walking.

Review of the Literature:

Legett and Flenley (18) studied the performance of 26 patients with chronic bronchitis and cor pulmonale during 12-minute walking tests (12-MWT) that were performed indoors. They were given liquid oxygen at a rate of 2 litres per minute (L/Min.) or 4L/Min. or compressed air in a single-blind fashion. During the walking tests, the liquid oxygen canister (4.2 kg) was

either assistant-carried, patient-carried (suspended from a shoulder), or pulled behind on a two-wheeled cart. They found a clinically modest but statistically significant improvement in distance walked (approximately 8% or 50 m) when the oxygen apparatus was carried by an assistant or transported on a two-wheeled cart compared to that achieved while breathing air. However, when the patients had to carry the load suspended from their shoulders, the gain in exercise tolerance provided by the supplemental oxygen was eliminated.

By contrast, Woodcock and coworkers (19) arrived at different conclusions than did Legett and Flenley (18) while studying 10 patients with severe COPD. Patients performed six-minute walking tests (6-MWT) while breathing compressed air or gaseous oxygen (4L/Min.) administered in a double-blind fashion. In contrast to earlier studies (14, 15, 17, 18) (including the one by Legett and Flenley), Woodcock and colleagues measured changes in breathlessness (visual analogue scale (28)) as well as exercise tolerance. During the walking tests the 2.5 kg gaseous cylinder was either assistant-carried or patient-carried. It was found

that, compared to air breathing, supplemental oxygen reduced breathlessness scores and, like the previous study, (18) it slightly increased the distance walked during the timed walking tests (approximately 14% or 36m). Patients walked an average of 320 m in six minutes when an assistant carried the oxygen cylinder and 306 m when the patient carried the load (a decrease of only 4.5% in distance). This difference was not statistically significant.

The conflicting results between these two studies may have been caused by the types of patients selected, the oxygen systems used, the duration of the walking tests, or by some combination of these factors. The earlier investigation by Legett and Flenley (18) chose severely hypoxic patients with cor pulmonale (mean partial pressure of oxygen in arterial blood (Pa02)= 52 mmHg), whereas Woodcock and colleagues (19) selected less hypoxic patients (mean Pa02 = 72 mmHg). Both studies chose different oxygen systems; Legett and Flenley (18) had the patients walk with a 4.2 kg liquid oxygen system (LOS) and for a longer period of time (12-MWT), whereas in the more recent investigation by Woodcock et al., patients carried a 2.5 kg gaseous

oxygen cylinder for half that time.

These differences in disease severity and study design between the two investigations may account for the lack of benefit shown by the patients in the Legett and Flenley study (18) when they had to carry the oxygen apparatus.

The potential of a portable oxygen system to increase the metabolic demand on a patient while carrying the apparatus was studied by Brambillia et al. (29). They looked at a group of eight patients (all with cor pulmonale, six with severe COPD and two with kyphoscoliosis) while performing incremental treadmill exercise breathing 30% oxygen with and without a 4.2 kg liquid oxygen pack suspended from a shoulder. They found a small, clinically insignificant 6% increase in carbon dioxide production ($\dot{V}CO_2$) when patients walked while carrying the oxygen apparatus compared to when patients walked without carrying the unit.

It was unclear from the methodology whether Brambillia and coworkers (29) allowed the patients to support themselves on the treadmill handrails during the walking tests. This manoeuvre has been shown to decrease the metabolic demand and to increase exercise

tolerance in healthy subjects (30) and in patients with cardiovascular disease (31). If handrail support was allowed in this group of patients, then the carbon dioxide production while carrying the oxygen pack may have been underestimated.

Unfortunately, Brambillia and associates (29) did not measure breathlessness during their investigation. Since dyspnea is one of the primary limiting factors to performing activities of daily living in patients with COPD (26), its measurement would have been helpful to assess the impact of load carriage on the perceived amount of energy that is required to perform a task.

In support of the findings by Woodcock et al. (19) and Brambillia and colleagues (29), Lock and coworkers (5) looked at the impact of using a 3.5 kg liquid oxygen pack compared to using a 2.5 kg gaseous oxygen cylinder (both delivering oxygen at 2 L/Min.) during assistant-carried and patient-carried modes of transport on 15 patients (13 with severe COPD).

As part of the selection criteria for the study, only patients showing at least a 10% improvement with supplemental oxygen during the 6-MWT and/or breathlessness score (visual analogue scale (28)) were

accepted.

Lock and colleagues (5) found that there was no significant difference in the median patient walking distance (255 m) regardless of the type of oxygen system transported. Also, walking performance was not significantly hindered by the weight of the oxygen delivery systems since walking distance and breathlessness scores (without reporting the dyspnea data) were comparable whether patients carried the oxygen themselves or had an assistant carry the load.

The patients in the Lock et al. study (5) were proven "responders" to the beneficial effects of supplemental oxygen (ie. enhanced exercise tolerance and/or decreased dyspnea). A previous study by Morrison and Stovall (8) on patients with severe COPD showed that the increased exercise capacity demonstrated by "responders" was accompanied by significant improvements in peripheral oxygen delivery (an increase in arterial oxygen content and cardiac output). None of these factors improved in the non responders. It did not appear that the patients in the Legett and Flenley study (18) were prescreened for enhanced exercise capacity with supplemental oxygen.

Since the beneficial response to portable oxygen is highly variable in hypoxic patients with COPD (6, 23), this may account for the lack of improvement (ie. walking performance) in their study (18) when patients had to carry the oxygen delivery system.

Also, the patients in the Legett and Flenley (18) investigation had to perform a walking test of longer duration than did patients in the Lock et al. study (5) (12 minutes versus six minutes) and patients in the Legett and Flenley investigation (18) had to carry a heavier load than did the patients in the Lock et al. study (5) (4.2 kg versus 3.5 kg). These factors may have influenced the outcome.

In contrast to these studies, Westmiller and Hoffman (27) studied the benefits of an assistive device - the four-wheeled cart, compared to the assistant-carried mode of oxygen transport during the 12-MWT by patients with severe COPD. Neither the oxygen flow rate nor the type (and weight) of the oxygen system were specified. However from the picture which appeared in their manuscript, it appeared that a 4.3 kg liquid oxygen pack was used. They found that patients walked significantly further with the

assistive device compared to the assistant-carried method (approximately 10% or 46 m). The improvement seen with the use of the four-wheeled cart was even greater when a subset of the sample of patients was studied (ie. patients unable to walk greater than 305 m during the 12-MWT). This group walked approximately 225 m (46% increase) further with the device than when the oxygen apparatus was carried by an assistant. Unfortunately Westmiller and colleagues (27) did not measure dyspnea during the walking tests or the distance with the patient-carried mode of oxygen transport (i.e., oxygen pack suspended from the shoulder). This would have helped to quantify the perceived impact of transporting a supplemental oxygen apparatus by different methods.

It seems apparent from Westmiller and Hoffman's investigation (27) that the more disabled the patients with COPD are, the more likely they would benefit from an assistive device such as a cart to transport the oxygen system. This finding supports the results reported by Legett and Flenley (18) who found that walking distances during the 12-MWT were restored to the level attained by the assistant-carried mode of

oxygen transport when a two-wheeled cart was used.

With the exception of the Brambillia et al. study (29), the other investigations that were reviewed measured the benefit of supplemental oxygen by the patients' performances during the timed walking tests (distance walked and/or breathlessness score). Various researchers have shown that there is a strong tendency for patients to improve their walking distance during timed walking by 8% to 33% with repeated testing (32-35). These authors have concluded that to attain reliable walking test results over a short interval (three to five days), patients should perform three to five practice walks prior to their baseline test. Clinically, whether patients could perform that many tests without undue fatigue is unclear. With the exception of the study by Westmiller and Hoffman (17), the "learning effect" that occurs with successive walking tests was not controlled in the other investigations.

Verbal encouragement that is given to patients by the testers during timed walking tests has been shown to significantly improve their performance (36). Of the studies reviewed, it seems that the Westmiller and

Hoffman study (27) was the only one to control for this effect.

Two outcomes which are typically measured when looking at the benefits of supplemental oxygen are the distance walked during the timed walking test and the level of breathlessness. However when walking velocity is not controlled, the interpretation of the results obtained while ambulating with two oxygen systems by three transport methods is difficult since walking rate may be influenced by the patients' preconceived notions. So, for example, if they dislike the CGOS "E" cylinders, they may walk less distance with this apparatus (compared to the LOS), they may report greater breathlessness, but unexpectedly, they may have a lower heart rate (HR) and higher arterial oxygen saturation (SaO_2) compared to the lighter LOS. Woodcock et al. (19) acknowledges that this problem exists with the interpretation of the results of timed walking tests.

In contrast, walking tests performed at a constant velocity (with the pace selected by the patient) over a set distance may provide more objective and reliable results than would a timed walking test since the

physiologic dependant variables (HR and SaO_2) would be less influenced by patients' preconceived notions. Also, since patients with COPD are known to walk at a remarkably steady pace (37, 38), possibly a patient-selected walking velocity would be a more valid measure of the "real life" situation.

The physiologic strain that is associated with walking with oxygen delivery systems was determined in this thesis by measuring heart rate and arterial oxygen saturation and by calculating oxygen uptake ($\dot{V}O_2$) during the walking tests. Because there is generally a linear increase in heart rate as workload increases (39, 40) in both normal subjects and in patients with COPD, the use of this parameter is justifiable. Although arterial oxygenation in patients with COPD may change in a variable fashion during exercise (increase, decrease or remain constant (41)), the majority of patients in this thesis experienced worsening hypoxemia with exercise. So it was decided that $Sa0_2$ values would provide a reasonable estimate of physiologic stress.

Because every patient participating in this thesis was on continuous supplemental oxygen (which was

delivered by nasal cannulae), it would have been impossible to measure oxygen uptake directly with a portable oxygen consumption device during the corridor walking tests. Instead, $\dot{V}O_2$ was determined by metabolic testing during the treadmill exercise tests. Since there is generally a linear relationship between HR and $\dot{V}O_2$ during exercise below the anaerobic threshold in normal subjects (42-44) and in patients with COPD (45, 46), it was possible to predict the metabolic cost of walking with liquid or gaseous oxygen by various transport methods. During maximal exercise in normal subjects, there is approximately a 7% source of error ($\pm$) in the determination of $\dot{V}O_2$ maximum (44). To the best of my knowledge, the magnitude of the source of error in predicting submaximal $\dot{V}O_2$ from HR values in both normal subjects and patients with COPD has not been determined.

Most of the studies reviewed used the visual analogue scale (28) to measure levels of dyspnea. This instrument consists of a 10 cm line on a page with the two extremes marked "not breathless" and "extremely breathless". As patients walk with the oxygen apparatus they place a mark on the scale that

corresponds to their momentary level of breathlessness. Research has shown that the results from this scale are quite reproducible in the short term but become less so over longer periods (weeks) in both normal subjects and patients with COPD (47, 48). It was felt that this scoring procedure was too difficult to manage for the severely disabled patients participating in this thesis. As an alternative, a numerical rating scale, the modified Borg scale (49), originally developed by Borg (50) to measure perceived exertion and later modified to measure breathlessness (49), was used to measure dyspnea. The modified Borg scale consists of 12 points, 10 of which have verbal descriptors of increasing subjective intensity from 0, or no dyspnea, to 10, or maximal dyspnea (see Appendix 1). While walking, patients can verbalize the number which best describes their level of dyspnea.

The modified Borg scale has been used by various researchers to quantify breathlessness when evaluating the beneficial effects of supplemental oxygen (6, 16), to test exercise capacity (38, 51), and to quantify the sensation of respiratory muscle effort (52, 53).

The reproducibility of the measurements from this

numerical scale are controversial. Muza and coworkers (48) measured dyspnea (modified Borg scale) in 10 healthy subjects exercising on a cycle ergometer on two separate occasions on the same day and found no significant differences in breathlessness scores. However, dyspnea scores reported on the second day of testing were reduced by 16% compared to the first day values.

The tendency for breathlessness ratings to diminish with repeated testing on separate days was also found by Belman et al. (54). They studied nine patients with moderate to severe COPD while they exercised to their perceived maximum on a motorized treadmill on four occasions over a 10 day period. Although various metabolic measurements (heart rate, minute ventilation) had stabilized during successive trials on the treadmill, Borg ratings decreased with successive tests.

Killian and coworkers (51) arrived at different conclusions about the reliability of the modified Borg scale than did Muza and colleagues (48) and Belman and associates (54). They examined the reliability of this instrument on 90 patients with COPD undergoing 120

maximal exercise tests on a cycle ergometer and found no significant difference in breathlessness scores between successive tests.

The modified Borg scale was used in the present thesis because of its ease of administration, its widespread use in other studies on patients with COPD, and its ability to quantify breathlessness.

SUMMARY OF THE LITERATURE

(a) Many studies have investigated the beneficial effect of portable oxygen. Clearly, a number of patients with advanced COPD derive genuine benefit from this therapy (improved exercise tolerance and reduced levels of dyspnea). When the improvement is measured in distance walked during the timed walking tests or breathlessness by the visual analogue scale, the magnitude of benefit is small.

(b) While there is useful supportive evidence that a portable oxygen apparatus carried by a patient does not impose a significant handicap, there is sufficient evidence to the contrary to merit further study.

(c) Comparisons of the benefits of supplemental oxygen between studies are difficult, owing to the differences between patients' severity of illness, and

study design.

(d) When timed walking tests are used to measure walking performance, control of the "learning effect" and the "effect of encouragement" must be considered in order to obtain reliable results.

(e) Oxygen consumption can be calculated from cardiac frequency during submaximal exercise. The accuracy of extrapolating $\dot{V}O_2$ during submaximal exercise has not been determined.

(f) Breathlessness can be measured in patients with COPD. The modified Borg scale is used for this purpose and is reasonably reliable.

Purpose:

Relatively little research has been conducted to examine the physiologic and perceptual stress associated with transporting oxygen delivery systems in patients with COPD. In fact, no researchers have compared the metabolic and perceptual costs of walking with the commonly used cast iron gaseous "E" cylinders to the lighter liquid oxygen packs. Nor have they studied the magnitude of the impact of carrying the liquid oxygen system on the shoulder versus pulling the oxygen unit on a two-wheeled cart. The purpose of this

thesis, therefore, was to compare the metabolic and perceptual responses during ambulation with two oxygen systems (gaseous and liquid) i.e., is there a difference in the amount of work done when walking with either oxygen system. Further, is one method of transporting the liquid oxygen (by the shoulder or two-wheeled cart) less demanding than the other.

Hypotheses:

1. The metabolic and perceptual demand of pulling the CGOS ("E" cylinder) on a two-wheeled cart will be greater than pulling the LOS pack on a two-wheeled cart.
2. The metabolic and perceptual demand of carrying a LOS pack suspended from the shoulder will be greater than pulling the LOS on a cart or carrying it by an assistant.
3. Walking on a motorized treadmill while carrying a liquid oxygen pack will be more demanding (metabolically and perceptually) than walking without the oxygen unit.

METHODS

Patients:

A group of 13 male patients with severe COPD were selected from referrals to the Pulmonary Rehabilitation Program and the Respiratory Home Care Program at the Aberhart Centre. It was felt that this sample was a good representation of the Alberta population of elderly male patients with severe airflow obstruction and pulmonary abnormalities suggestive of emphysema. Three patients were excluded from the thesis - one whose cardiac response was limited by discomfort from the non-rebreathing value mouthpiece and two whose heart rate response during the corridor walking tests was outside the bounds of their HR-$\dot{V}O_2$ regression relationship achieved during the treadmill walking tests. Therefore, data analysis was done on 10 patients.

This investigation was approved by the University of Alberta Research Ethics Board and Special Services and Research Committee at the University of Alberta Hospitals. The Physical characteristics of the patients are recorded in Table 1. The inclusion criteria were that participants must (1) be on long-

term oxygen therapy (sometime during the 24 hour period); (2) have a forced expiratory volume in one second (FEV_1) to forced vital capacity (FVC) ratio of <0.7, and FEV_1 <70% of predicted; (3) have the ability to ambulate 255 m nonstop carrying a full liquid oxygen pack (4.3 kg) suspended from a shoulder; (4) be clinically stable (as determined by a pulmonologist); (5) be able to maintain (by adjusting oxygen flow) an arterial oxygen saturation of $\geq$ 90% during the walking tests while on supplemental oxygen; (6) be free of other medical conditions that may inhibit exercise performance and/or make testing unsafe (eg. angina, diminished cardiac function, neurological, psychological, or locomotor dysfunction); and (7) provide their informed consent.

A pilot study using four of the 10 patients in the study group was done first to establish within - subject variability, to ensure that the techniques used (corridor walking tests performed at a constant velocity and motorized treadmill walking) could be performed by this group of patients, and to quantify the physiologic and perceived energy cost of walking with portable oxygen devices (liquid and gaseous).

Procedure:

This thesis consisted of five phases: (1) a pre-investigation assessment and familiarization session; (2) pulmonary function testing prior to and following the investigation; (3) corridor walking tests; (4) treadmill walking tests; and (5) completion of a patient questionnaire at the end of the study.

Pre-Investigation Testing and Familiarization (see Appendices 2 and 3):

A pulmonologist and the author assessed the patients in the Physiotherapy Department at the Aberhart Centre to ensure that they met the inclusion criteria. The procedures and attendant risks were explained and written informed consent was obtained (see Appendix 4). Although the patients agreed to perform 300m walking tests (as was stipulated in the consent document), all patients performed 255 m tests. The distance was shortened prior to the study because some of the patients were too disabled to walk 300 m.

Next, the patients were familiarized with the modified Borg dyspnea scale (a numeric scale ranging from 0-10, (49) and then fitted with a wireless heart rate monitor (Sport Tester Polar Vantage XL™).

Following this, they practiced walking in the hospital corridor with the liquid oxygen pack (suspended from the shoulder or pulled on a two-wheeled cart) and the gaseous "E" cylinder (pulled on a two-wheeled cart (Table 2). The patients became accustomed to reporting their level of breathlessness using the modified Borg Scale (49) as well as walking at a constant velocity (with minimal coaching from the assistant). During the practice walks the assistant determined the oxygen flow rate required to maintain the $Sa0_2$ at 90% or greater in those patients who desaturated during exercise.

In addition, for those patients not familiar with walking on a motorized treadmill (Quinton 55™), a 10 minute practice session was done during the introductory phase of this investigation.

Testing Protocol:

During the first week of the study the pilot patients performed four corridor walking tests - one with the liquid oxygen pack carried from the shoulder, one with the liquid oxygen pack pulled on a two-wheeled cart, one with the gaseous "E" cylinder pulled on a two-wheeled cart, and one with the oxygen apparatus carried by the assistant (the control). Supplemental

oxygen was delivered through nasal cannulae for all of the corridor walking tests. The patients also performed two submaximal, incremental, treadmill walking tests - one while carrying the liquid oxygen pack and one without having to carry the pack. In both cases, there was no oxygen flow from the liquid oxygen pack since the increased FIO_2 was supplied by an oxygen blender and inhaled through a mouthpiece. The four pilot patients participated in the thesis three days per week and performed two walking tests per session with a 20 minute rest between walks. It was felt that a 20 minute rest between walking tests was sufficient time for patients to recover. The 20 minute rest interval has been used by previous researchers who showed reproducibility of corridor walking tests (32, 36). Other investigators studying the impact of walking with oxygen delivery systems on patients with COPD during timed walking tests have used the 30 minute rest interval (18, 19, 27). Since the patients in this thesis performed corridor walking tests at a self-selected "comfortable" pace, theoretically the tests in this thesis would be less fatiguing so patients would require less of a rest between tests then after timed

walking tests. The same rest interval used during the corridor walking tests was used during the treadmill walking tests since the intensity of exercise during the treadmill tests was similar to that of the corridor tests (ie. patients' maximum HR was similar for both tests). Also, there was a desire to keep the rest interval for both tests the same for the sake of consistency between tests. During week one, the order of testing was randomized and then the same order was maintained for repeat testing in week two (Table 3).

The main study group followed the same protocol as that of the pilot group with the exception that there was no repeat testing on the second week (ie. they performed four corridor walking tests and two treadmill tests).

Pulmonary Function Testing:

Patients underwent pulmonary function testing prior to the thesis to ensure that they met the inclusion criteria. Selected patients also completed pulmonary function testing following the investigation to determine if there was a significant change in their pulmonary status during the study. The patients' FVC and FEV_1 were measured using a water sealed spirometer

(Gould 2400™). Their functional residual capacity (FRC), total lung capacity (TLC), and residual volume (RV) were measured using the helium-dilution technique (55). The diffusion capacity for carbon monoxide (DLCO)/VA (alveolar volume)) was measured with the single breath method (56). Predictive normal values were obtained for FEV_1 and FVC from Morris et al. (57), lung volumes from Crapo et al. (58), and diffusing capacity from Miller et al. (59). Also, 12-lead electrocardiography (ECG) testing was performed on all patients (at rest) during the initial visit to the pulmonary function laboratory.

Corridor Walking Tests (see Appendix 5):

All testing was done on an individual basis by one assistant and at approximately the same time each morning. The patients were instructed to (a) maintain their current medication regimen during the study, (b) refrain from smoking, ingesting caffeine products and exercising in the two hours prior to testing, (c) walk at a self-selected, comfortable pace, (d) avoid speaking during the walking tests (except to report the numerical rating of their breathlessness), (e) pull rather than push the supplemental oxygen two-wheeled

carts, and (f) pull the carts from the same side for each test.

The liquid oxygen pack (Cryogenics-Stroller™) was refilled before each walking test and the gaseous "E" cylinder with regulator and flowmeter (Chemtron™) was weighed prior to each test. A suitable amount of weight was added to the "E" cylinder cart (Variflow™) to ensure that the patients were always exercised with the same weight of the oxygen system. When full of oxygen, the liquid oxygen pack weighed 4.3 kg, the oxygen pack plus two-wheeled cart (Cryogenics™) weighed 6.6 kg, and the "E" cylinder (including regulator, flowmeter and two-wheeled cart) weighed 10.6 kg (Table 4).

The same liquid oxygen pack and gaseous oxygen regulator and flowmeter were used for all of the walking tests. The flow rate delivered by the gaseous oxygen system was checked regularly with a calibrated flow meter.

Patients walked back and forth in an empty hospital corridor that was 85 m in length at a self-selected pace over the 255 m distance for the first walking test and at the same velocity for the

subsequent tests. Constant velocity walking by the patients was accomplished by first establishing the time (at 85 m intervals) needed to walk 255 m during the initial walk, and then during the subsequent walking tests, the patients were prompted by the assistant to speed up or slow down in order to maintain the same pace. Patients were accompanied by an assistant during the walking tests who pushed a four-wheeled cart on which was carried (a) the pulse oximeter and printer (Nonin 8604™ and 8604P™ respectively), (b) a heart rate receiver (Sport Tester Polar Vantage XL™), (c) a clipboard with the modified Borg Scale (49) attached, and (d) the oxygen supply used during the assistant-carried mode of oxygen transport. The assistant refrained from giving encouragement during the walking tests or from allowing patients to see the oximetry values since this may have influenced the patients' perceived sense of breathlessness during the tests. During the last 10 seconds of each minute of exercise the patients were shown the modified Borg scale and asked to verbalize the numerical rating that best described their perceived level of dyspnea at that moment. Once the

walking test was completed, heart rate and SaO_2 values (at 30 second intervals) were downloaded from the respective monitors. Elapsed time and breathlessness scores were also recorded on the data sheet (see Appendix 6). Mean values were calculated during steady state exercise (last 30 seconds) for the HR, SaO_2, and breathlessness scores. Finally, the surface electrodes from the heart rate transmitter were removed and then, after a brief rest, the patients were free to leave the testing centre.

Although the Sport Tester™ HR monitor has been shown to correlate well with the ECG HR during exercise (60), its accuracy was also assessed in this study (on one patient). To do this the patient exercised on two different occasions on the treadmill and HR was measured simultaneously using the Sport Tester™ and the ECG (see results).

Treadmill Walking Tests (see Appendices 7 and 8):

The purpose of this part of the thesis was to determine: (1) the metabolic and perceived demand of carrying a 4.3 kg liquid oxygen unit and (2) the individual linear regression prediction equations from the heart rate and oxygen uptake relationship (achieved

during treadmill walking with the liquid oxygen apparatus suspended from a shoulder). These equations were then used to calculate the oxygen uptake values that were achieved during the corridor walking tests by substituting the mean heart rate values for the final 30 seconds during the corridor walking tests into the individual linear regression equations (see Appendix 9).

Prior to the patient's arrival in the laboratory the metabolic cart was calibrated. This involved volume calibrations using a calibrated syringe and precision gases for calibration of the O_2 and CO_2 analyzers.

Upon arriving at the exercise laboratory, patients had ECG electrodes applied for continuous monitoring during the exercise tests. They were randomly allocated to perform two walking tests on the treadmill at the same velocity and grade - one while carrying the oxygen apparatus and the other without any load. There was a 20 minute rest between tests. The patients were exercised to the same maximal heart rate as had been achieved during the corridor walking tests. They breathed a mixture of oxygen and room air from a

meterological balloon which was connected to an oxygen blender (Ohio Air-Oxygen Proportioner™). With the exception of one patient, the fractional oxygen concentration (FIO_2) delivered to the balloon was approximated from the flow of oxygen from the liquid oxygen packs during the corridor walking tests and converted to the FIO_2 (from Table 5, (61)) so that a mixture was achieved of similar concentration to that provided by the liquid oxygen delivery system. For patient number eight, the treadmill exercise tests preceded the corridor walking tests. The FIO_2 for the treadmill tests was approximated from the oxygen flow rate used during the familiarization session. The oxygen flow rate for the corridor tests was then approximated from the treadmill FIO_2 (Table 5).

After resting for a minimum of 10 minutes prior to the test, the patients stood on the treadmill deck and began breathing through a non-rebreathing valve (Hans Rudolph model 2700™) for four minutes while the metabolic cart (Sensor-Medics Horizon System™) measured the fraction of oxygen in the inspired air and achieved stable readings. They then began walking on the treadmill at 1 mile per hour (MPH) and had the

speed increased by .5 MPH at 2 minute intervals up to a maximum speed of 2.5 MPH. If the target heart rate (maximum heart rate achieved during the corridor walking tests) was still not achieved after reaching 2.5 MPH, the treadmill grade was elevated by 2 percent every minute to a maximum grade of 10 percent.

The fraction of oxygen and carbon dioxide (CO_2) in the mixed expired gas and minute ventilation ($\dot{V}E$) were analyzed by an oxygen sensor, a CO_2 analyzer, and a turbine flow meter respectively, located in the metabolic cart. $\dot{V}E$, $\dot{V}CO_2$, and $\dot{V}O_2$ were calculated on-line by the metabolic cart computer and the results were averaged for every 30 seconds. Oxygen saturation was measured by a pulse oximeter (Ohmeda Biox 3700™) with a finger probe clipped to the left index finger. Heart rate and ECG tracings were recorded continuously (Hewlett-Packard Pagewriter 4700™). The same pulmonary function technician operated the metabolic cart, the treadmill, and the monitoring equipment for all of the treadmill walking tests. The assistant from the corridor walking tests recorded the dyspnea scores at one minute intervals using the modified Borg Scale (49) which was posted in front of the patients.

Because of their advanced age and level of disability, all patients held the siderails of the treadmill during the walking tests. Therefore, there was some support during the unloaded walk and the walk where the oxygen pack was carried over the shoulder.

Patient Survey:

After completing the study, all patients were asked for their written response to a series of questions (see Appendix 10) designed to determine the perceived "energy cost" of ambulating with the two oxygen systems transported by various means.

Design:

This study employed a repeated-measures design. The independent variables were the type of oxygen system (liquid versus gaseous) and the transport methods (by shoulder, by cart, or assistant-carried). The dependent variables were the objective and subjective measures of the physiologic and perceptual cost to perform a task: HR, SaO_2, $\dot{V}O_2$, $\dot{V}CO_2$, and breathlessness scores.

Overall mean data, regression values, and graphics were generated using Lotus 1-2-3 (versions 2.2 and 3.1) and Lotus Freelance on an IBM compatible. Analysis of

variance (ANOVA) values and power values were calculated using the Statistical Package for the Social Sciences (SPSS) software.

Linear regression techniques were used to examine the relationship between the variables of interest and to calculate oxygen consumption from HR data. The data collected for each variable were analyzed using repeated-measures one-way analysis of variance. The Bonferoni multiple comparison procedure was used to isolate the mean values contributing to any significant F-ratios. A probability value of less than 0.008 (0.05/6) was considered significant whereby the probability (0.05) was divided by the number of possible combinations of oxygen transport methods (six) with the two oxygen systems. The six combinations were: CGOS vs. LOSSH, CGOS vs. LOS-2WC, CGOS vs. AC, LOSSH vs. LOS-2WC, LOSSH vs. AC, and LOS-2WC vs. AC. The regression correlation technique was used in the analysis of the pilot group data. Paired student t-test analysis was carried out to compare (1) the slopes from the regression equations of the pilot group (test one versus test two), (2) the $\dot{V}O_2$, $\dot{V}CO_2$, and breathlessness values obtained during the treadmill

tests while walking with and without an oxygen pack, (3) pre-study and post-study pulmonary function test results, and (4) HR values from the Sport Tester™ vs. the ECG, and SaO_2 values achieved on the treadmill compared to the corridor tests. A probability value of $<.05$ was considered significant.

RESULTS

Patients:

Physical characteristics and results of the baseline pulmonary function tests are presented in Table 1. The group consisted of 10 males whose mean age was 68.8 ± 6.3 years. The patients had severe airflow obstruction with a mean FEV_1 of 0.95 ± 0.24L, and a mean FEV_1/FVC of 36.6 ± 8.8% of predicted. They were significantly hyperinflated with a mean FRC of 4.63 ± 1.12L which was 179.8 ± 35.6% of predicted. The diffusion capacity was also significantly reduced (DLCO/VA= 60.4 ± 21.4% of predicted).

Validation of the Portable HR Monitor:

The results of the Sport Tester™ were compared to the output from the ECG (Hewlett-Packard pagewriter 4700™) on one patient while performing two exercise tests on the motorized treadmill. During both exercise tests, the patient wore the electrodes from both monitors and HR was measured at 30 second intervals for 7.5 minutes.

Heart rate measurements recorded by the portable unit were similar to those obtained by the ECG (Table 6). During the first exercise test while the patient

carried the oxygen unit the mean HR recorded by the Sport Tester™ was 97.8 ± 9.9 bpm and by the ECG 96.6 ± 9.3 bpm. The data from the monitors were highly correlated ($r = 0.97$) and are graphically illustrated in Figure 1. The paired t-test revealed that there was no significant difference between the methods of HR measurement ($t_{(15)} = 2.56$, $p>0.05$, 2-tailed). The degrees of freedom (number of difference values minus one) are shown in parenthesis.

The average HR during the second exercise test measured by the Sport Tester™ and ECG was 91.3 (± 7.7) and 91.9 (± 7.2) respectively (Table 6). These results were also highly correlated ($r=0.94$); this relationship is displayed in figure 2. Again, there was no significant difference in the HR values recorded by the two monitors ($t_{(15)} = 0.63$, $p > 0.05$).

Repeated Exercise Testing:

The mean values for HR, $\dot{V}O_2$ (calculated), SaO_2, and breathlessness achieved during the corridor walking tests by the four pilot patients performed on two separate occasions are reported in Table 7. The reproducibility of the variables of interest for this group of patients was inconsistent (based on sample

mean and correlation calculations; Table 7). Correlation coefficients were calculated for HR, breathlessness, SaO_2, and $\dot{V}O_2$ (calculated) obtained during the corridor walks. The values were taken at the same time during walks one and two. This was done for each of the four patients. The correlation values ranged from 0.68 to 0.98 for HR, 0.09 to 0.77 for calculated $\dot{V}O_2$, 0.009 to 0.89 for SaO_2 and 0.09 to 0.77 for breathlessness. Because of the small pilot patients sample size (low power), further data analysis to determine reliability was not possible.

Corridor Walking Tests:

The cardiovascular, metabolic, and perceptual responses during the walking tests by the 10 patients are summarized in Table 8. The analysis of variance indicated that there was no significant difference ($p>0.05$) in the $Sa0_2$ values during the corridor walking tests using the three transport methods (Table 8). However, the $Sa0_2$ values tended to be lower with the CGOS and LOSSH modes of oxygen transport (88.7% and 89.9% respectively) when compared with the AC and LOS-2WC methods of oxygen transport (90.3% and 90.3% respectively; Figure 3).

Table 9 shows that four of the 10 patients experienced a significant degree of exercise-induced hypoxemia (SaO_2 < 90%) during the corridor walking tests (patient number #1, 2, 3 and 8). Of this group, one patient (#1) exercised at the maximal supplemental oxygen flow rate (5L/min.) while three patients (#2, 3 and 8) were exercised on an oxygen flow rate which unfortunately failed to raise SaO_2 values to at least 90%.

A comparison of the average arterial oxygen saturation achieved at the end of exercise during the corridor walking tests and at the same time during the treadmill tests revealed a significant difference ($t_{(9)} = 4.41$, $p < 0.05$, two tails). Saturations were lower in the corridor (mean = 89.8 $\pm$ 3.5%) compared to the treadmill (mean = 95.0 $\pm$ 1.5%, Table 10) tests.

The impact of transporting an oxygen delivery system on HR, $\dot{V}O_2$ (calculated), and breathlessness is seen in Table 8 and is demonstrated in Figures 4, 5, and 6. The analysis of variance showed that there were significant differences ($p<0.01$) in some of these variables during the four modes of ambulation (Table 11). The results of the post hoc analysis are

presented in Table 12. As expected, the physiologic stress (as assessed by HR and $\dot{V}O_2$) associated with transporting an oxygen delivery system was significantly less ($p<0.05$) when an assistant carried the oxygen pack (the control) compared to pulling the gaseous "E" cylinder or carrying the oxygen pack. Mean HR was 5.9% lower than with the CGOS and 3.9% lower than with the LOSSH method (Fig. 4). The average decrease in the calculated $\dot{V}0_2$ for the AC method vs. the CGOS and LOSSH methods was 20.8% and 16.5% respectively. There were no significant differences in HR or $\dot{V}0_2$ when the other methods of oxygen transport were compared.

Mean dyspnea scores were significantly different ($p<0.05$) when walking with liquid oxygen (suspended from the shoulder) vs. the AC method or the gaseous oxygen compared to the AC method (Table 8 and Fig. 6). Table 12 summarizes the pair-wise comparisons. The reported intensity of breathlessness was significantly higher when patients walked with the CGOS and LOSSH (3.2 vs. 2.3 and 2.9 vs. 2.3 respectively) compared to the AC method. Breathlessness scores were not significantly different for the other methods of oxygen

transport.

Table 11 shows that post hoc power tests were excellent for breathlessness (0.99), HR (0.98), and $\dot{V}O_2$ calculated (0.94), but poor for SaO_2 (0.73).

Treadmill Walking Tests:

There was a significant increase in peak oxygen uptake (9.7%) and in carbon dioxide production (11.7%) when patients walked on the treadmill carrying the liquid oxygen pack (4.3 kg) compared to walking on the treadmill without the oxygen unit ($t_{(9)} = 3.45$, $p<0.05$; $t_{(9)} = 2.66$, $p<0.05$, two-tails respectively; Table 13). There was no significant difference in breathlessness scores while walking on the treadmill with and without a load.

Analysis of the $\dot{V}O_2$ - HR relationship during incremental exercise on the treadmill (while carrying the LOS) showed a linear pattern with a wide range of slopes (Table 14). Linear regression analysis demonstrated that these two variables were highly correlated in each patient (mean $r^2 = .89$; Table 14). A comparison of the regression equation slopes of the pilot group during the first and second treadmill tests showed that there was no significant difference at the

$p>0.05$ level of significance (Table 15). However, correlation analysis showed a poor relationship (r^2 = 0.02) during the test-retest linear regression procedure. This poor correlation implies that $\dot{V}O_2$ calculated values cannot be reliably predicted from HR values in this study group. However, in reality, the poor correlation resulted from the small scatter of slope values amongst the four patients.

Pulmonary Function Tests:

The initial and final pulmonary function test results for all the subjects (a measure of clinical stability during the thesis) are shown in Table 16. Patients were not exercised on the day of the initial pulmonary function tests; however, they performed a treadmill exercise test on the same day prior to the final pulmonary function testing. Paired t-test analysis showed a small but significant difference in the initial and final FEV_1 ($t_{(9)}$ = 3.72, $p<0.05$) and FVC ($t_{(9)}$ = 2.43, $p<0.05$, two-tails). FEV_1 decreased from a mean value of 1.06L to 0.83 and FVC decreased from 2.87L to 2.55L between the initial and final tests.

Questionnaire:

Firstly, as reported in table 17, six out of 10

patients (60%) said they found that pulling the CGOS on a two-wheeled cart more energy demanding than pulling the LOS on a two-wheeled cart; four patients (40%) perceived no difference in the burden of those two oxygen systems. This ambivalent response toward the two oxygen systems was in agreement with the physiologic and perceptual results of ths thesis. Secondly, the majority of the patients (8/10 = 80%) reported that carrying the LOS suspended from the shoulder was the most energy demanding of the modes of oxygen transport followed by pulling the CGOS. The physiologic and perceptual results of this thesis (although not statistically significant) were opposite to the survey results (ie. walking with the CGOS seemed to be more "energy demanding" than the LOSSH method).

Finally, there was universal agreement amongst the patients that the AC mode of oxygen transport was the least "energy demanding". This perception was supported by the physiological findings of this investigation.

All but one of the patients preferred the LOS over the CGOS for outings. The most common reasons sighted were the enhanced portability of the LOS compared to

the CGOS (i.e. the LOS is lighter and can be carried if the need arises), the enhanced maneuverability of the LOS, and the capability for refilling the LOS in the home.

The patient who favoured the CGOS qualified this choice by stating that he preferred the aluminum "D" cylinder coupled with an oxygen conserving device (total weight approximately 4 kg) to the LOS since the CGOS does not leak when not in use (unlike the LOS).

DISCUSSION

Portable oxygen is inconvenient, expensive, and difficult to manage during ambulation. However, supplemental oxygen has been shown to have important benefits for patients with severe COPD including a decreased mortality rate, improvement in exercise tolerance, and reduction in breathlessness. In many investigations demonstrating the efficacy of supplemental oxygen (over air-breathing), patients did not have to carry the oxygen delivery system since they were exercised on a treadmill or bicycle ergometer (6, 14-17). In studies where patients had to carry the oxygen apparatus, the improvements in walking distance were of relatively small magnitude (5, 18, 19). Since exercise tolerance is often severely curtailed in patients with advanced lung disease, it is important that the oxygen delivery system does not further handicap walking performance.

This thesis compared the metabolic and perceptual cost of walking with the gaseous "E" cylinder vs. walking with the liquid oxygen pack. Further, to help quantify the impact of ambulating with a liquid oxygen system, the shoulder, cart, and assistant methods of

oxygen transport were compared.

There was no significant difference in the physiologic stress (as was determined by changes in HR, calculated $\dot{V}O_2$, and SaO_2) of pulling a 10.6 kg gaseous system ("E" cylinder plus regulator, flowmeter, and cart) compared to pulling a 6.6 kg liquid oxygen system (oxygen pack plus cart). However, the patients' HR, calculated $\dot{V}O_2$ values, and breathlessness scores tended to be higher with the gaseous system compared to the liquid oxygen system (especially when the LOS was pulled on a cart).

Post hoc sample size calcuations (62) were performed to help assess the significance of this trend (↑ HR, ↑ calculated $\dot{V}O_2$, ↑ breathlessness while walking with the CGOS vs. the LOS-2WC). Calculations were based on an alpha level of 0.05, a beta level of 0.2, and mean differences between dependent variables as indicated in table 8 (see Appendix 11 for calculations). Approximately 284 patients would have been needed to show a significant difference in HR, 180 patients to show a significant difference in calculated $\dot{V}O_2$, and 28 patients to show a significant difference in breathlessness.

With the exception of the assistant-carried mode of liquid oxygen transport, the other carrying methods for the LOS (by cart or by shoulder) offered no significant advantage (from a physiologic and perceptual standpoint) over one another. However, HR, $\dot{V}O_2$ (calculated), and breathlessness tended to be higher with the LOSSH method of transport. This trend was supported by the survey results where patients reported the shoulder mode of liquid oxygen transport to be the most energy demanding when walking with the two supplemental oxygen systems.

Since the mean differences for HR, calculated $\dot{V}O_2$, and breathlessness were of even less magnitude when comparing the LOSSH vs. the LOS-2WC methods of oxygen transport than were the mean differences for the same variables of interest for the CGOS vs. the LOS-2WC, post hoc sample size calculations were not warranted.

Because the corridor walking test protocol in this thesis allowed the patients to ambulate at their own "comfortable" pace, the physiologic (and perceptual) parameters most likely reflect the lowest values that could be expected (63). Perhaps a more vigorous walking test (of longer duration and/or ramps and

stairs) would have demonstrated a difference in the metabolic and perceptual impact of walking with the two oxygen systems.

Part of the explanation for needing such a large sample size to demonstrate significant differences in the dependent variables has to do with the small differences in the means in the variables of interest. So, although it would be possible to achieve statistically significant differences in HR, calculated $\dot{V}O_2$, and breathlessness scores with a larger group of patients, it is unlikely that these differences would be clinically significant.

It may be advantageous (from an energy conservation point of view) to relieve severely disabled patients with COPD of the added burden of the oxygen delivery system when ambulating. This may be accomplished by transporting the oxygen unit in a four-wheeled cart or by having an assistant carry the oxygen unit but, of course, the latter option is not possible in most circumstances.

To thoroughly evaluate the energy demand of performing a physical task, metabolic measurements such as $\dot{V}O_2$ are needed. Because it was not possible to

accurately measure $\dot{V}O_2$ with a portable monitor during the corridor walking tests while breathing an increased FIO_2 (patients on supplemental oxygen breathe a mixture of air and oxygen resulting in a variable FIO_2), patients performed incremental treadmill exercise while metabolic measurements were recorded. In this case $\dot{V}O_2$ could be measured since a constant FIO_2 was supplied by an air-oxygen blender and FIO_2 was monitored by the metabolic cart. By regression analysis of the HR-$\dot{V}O_2$ relationship for each patient achieved during treadmill exercise (carrying the liquid oxygen pack) it was possible to calculate the "oxygen cost" of walking in the corridor with the two oxygen systems (by substituting HR values achieved in the last 30 seconds of exercise during the corridor tests into the regression equations).

Although it is generally reported that there is a linear relationship between HR and $\dot{V}O_2$ below the anaerobic threshold in normal subjects (39, 42-44) and in patients with COPD (45, 46) we still found it necessary to visually inspect each treadmill HR vs. $\dot{V}O_2$ relationship to determine the range where these were linearly related. We found that the first one or two

minutes of exercise did not fit the HR-$\dot{V}O_2$ regression for the remaining five to six minutes of exercise. The regression equations used were determined within this linear region of values. This introduced a source of error into the calculation of the $\dot{V}O_2$ and was evident from the lack of a correlation between the slopes of the regression equations during repeat analysis of the pilot patients' data (Table 15). Analysis of the individual HR-$\dot{V}O_2$ relationships during incremental treadmill exercise revealed a nearly flat slope. This was caused by a rapid resting HR and a low peak HR in this group of patients and the low slope gave the potential for large errors in $\dot{V}O_2$ for small changes in HR. Other researchers have reported that patients with COPD have an elevated resting cardiac frequency (40, 64) and diminished maximum HR (46, 65). Possible mechanisms for an enhanced resting HR include: (a) a compensatory mechanism for hypoxemia (58, 66), (b) concomitant ventricular disease (45), (c) deconditioning (64), and (d) bronchodilator medications (65). The low HR maximum in these patients may be the result of patients interrupting exercise before the cardiovascular system is maximally stressed because of

a reduction in their ventilatory capacity (45).

Exercise-induced hypoxemia (SaO_2 < 90%) was experienced by four patients during the corridor walking tests in this thesis (Table 9). This was not preventible in patient number one since he was exercised on the maximum oxygen flow rate (5 L/min.). Possibly the hypoxemia in patients number two and number three could have been alleviated by upward titration of the oxygen flow rate (although patient number three was already near the maximum at 4 L/min.). Patient number eight was exercised on oxygen at 3 L/minute because the treadmill test, which preceded the corridor walking tests, showed his SaO_2 to be > 93% at an FIO_2 of 32%. From table 5 this corresponds to an oxygen flow rate of 3 L/minute. However a discrepancy in arterial oxygen saturation values was evident between breathing a constant FIO_2 through a mouthpiece from an oxygen blender (during treadmill exercise) and a corresponding oxygen flow rate from nasal cannulae (saturation on the nasal cannulae was consistently lower; Table 10). During exercise, ventilation is augmented by producing larger tidal volumes and by increasing the respiratory rate. When nasal canulae

are used during exercise, the larger tidal volume and tendency to breathe preferentially through the mouth lowers the FIO_2 (61) presumably by diluting the oxygen-enriched air with room air. Consequently, the guideline chart for estimating oxygen flow rate from FIO_2 and vice versa (Table 5) is only valid during resting conditions. Further research is needed to examine the validity of this chart and to produce a more appropriate one for exercise.

A significant difference was found in the initial and final pulmonary function test results (FEV_1 and FVC) in this group of patients (Table 15). The final measurements were consistently lower than the pre-investigation values despite no obvious clinical change in the patients. A possible explanation for this discrepancy may be that the patients' chest wall muscles were fatigued or their airways were more bronchospastic during the final pulmonary function tests since the testing was preceded by the treadmill exercise test. Both tests were scheduled on the same day for patient convenience. However, in retrospect, these tests should have been held on separate days.

A limitation of this study was the use of $\dot{V}O_2$

values from treadmill exercise to calculate $\dot{V}O_2$ values during corridor walking from HR data. Despite the shortcomings previously mentioned above, it is felt that the metabolic measurements helped quantify the physiologic impact of walking with an oxygen delivery system. Future controlled studies are needed to examine the reliability and validity of the predicted $\dot{V}O_2$ values determined in the manner described in this thesis.

This thesis found a statistically significant 11.7% increase in CO_2 production when patients had to carry the liquid oxygen apparatus on their shoulder (during treadmill walking) compared to "unloaded" walking. Although $\dot{V}CO_2$ correlates with $\dot{V}O_2$ at workloads below the anaerobic threshold, the use of $\dot{V}CO_2$ to represent metabolic demand is questionable especially at workloads above the anaerobic threshold. This value may be an underestimation of the true metabolic demand since the patients were allowed to support themselves by holding onto the treadmill handrails (which decreases the metabolic demand of the activity (30, 31). Brambillia and co-workers (29) used $\dot{V}CO_2$ to assess the work done during treadmill exercise

(using the identical oxygen equipment used in this thesis) in respiratory patients (six with COPD and two with kyphoscoliosis) walking with and without a load. They found an increase of 6% in $\dot{V}CO_2$. The difference in results between these two investigations could be due to differences in the patients selected. Brambillia and colleagues (29) tested younger patients (mean age 48.4 $\pm$ 10.5 years versus 69.8 $\pm$ 6.1 years) who may have been less disabled than this group. Also, the treadmill protocol varied - Brambillia et al. had patients walk for five minutes at 2 kmh and a 10% grade whereas the patients in this thesis walked from two to five kmh for from five to twelve minutes with and without a grade. Finally the FIO_2 varied between studies. Brambillia and co-workers exercised patients at an FIO_2 of 30% whereas the patients in this thesis were exercised at an FIO_2 that ranged from 28% to 40%.

Further research is needed to quantify the magnitude of the metabolic burden of walking with an oxygen unit. Greater levels of breathlessness were expected (but did not occur in this thesis) when patients had to walk pulling the "E" cylinder compared to pulling the liquid oxygen pack since the gaseous

unit is almost twice as heavy as the liquid apparatus. Also, the "E" cylinder has a higher center of gravity than does the liquid oxygen pack because of its shape and position of the flowmeter and regulator (on top). Consequently, a significant amount of weight is transmitted to the pulling hand of the patient during ambulation. This may lead to muscular fatigue and breathlessness. It is possible that the patients in this thesis may have experienced localized muscular discomfort while transporting the oxygen delivery systems (especially with the LOSSH and CGOS) which may have influenced the dyspnea ratings. In contrast to the gaseous "E" cylinder, the liquid oxygen pack has a low center of gravity, i.e. the majority of the weight of the apparatus is transmitted to the wheels of the two-wheeled cart making it theoretically easier to pull. Possibly a more demanding walking test (longer duration and/or ramps and stairs) would have produced a difference in the severity of dyspnea associated with transporting these oxygen systems.

Since the weight of a portable oxygen system can affect a patient's level of dyspnea during walking, possibly by limiting the weight of the oxygen delivery

apparatus by only filling the unit with the quantity of liquid oxygen required, or by carrying the equipment on a cart or by using a smaller gaseous "D" cylinder coupled with an oxygen conserving device (total weight = approximately 4.5 kg) breathlessness could be minimized.

It is difficult to compare the physiologic and perceptual results of this thesis with the results of previous studies due to differences in outcome measures, instrumentation, and study design. Previous researchers have used walking distance achieved during timed walking tests to assess the magnitude of the burden of an oxygen delivery system (5, 18, 19). Fewer investigators have attempted to quantify the level of dyspnea associated with carrying a load during walking (15). Clearly, studies are needed in the future which examine the physiologic and perceptual cost of ambulating with an oxygen apparatus. This should be done with a larger sample size than was used in the present thesis, with both sexes, and possibly with more physically- demanding walking tests than were used in this thesis. Having the ability to predict the magnitude of the burden of various oxygen delivery

systems on patients with COPD would be of great benefit to physicians who prescribe supplemental oxygen and allied healthcare providers who monitor the use of oxygen systems by patients in the community. The ambulatory supplemental oxygen system that maximizes the patient's mobility outside of the home would be determined by the strength, the endurance, the level of disability, and the financial state of the patient.

CONCLUSIONS

From a physiologic and perceptual standpoint, there was no significant difference in the impact of walking while pulling the gaseous "E" cylinder compared to pulling the lighter liquid oxygen canister in an enclosed hospital corridor over a 255m distance.

The assistant-carried method of liquid oxygen transport offered the only physiologic and perceptual advantage (reduced HR, reduced calculated $\dot{V}O_2$, and reduced dyspnea) compared to the CGOS and LOSSH methods of oxygen transport.

Survey results indicated that patients perceived the shoulder method of liquid oxygen transport as being the most energy-demanding followed by pulling the gaseous "E" cylinder.

Finally, the additional weight of a liquid oxygen system carried from the shoulder imposed a significant increase in the metabolic burden in COPD patients walking on a motorized treadmill.

IMPLICATIONS OF THIS THESIS

1. Further studies are needed that evaluate the benefit of portable oxygen. The investigations should be done with the patients carrying the oxygen system while perceptual and physiologic parameters are measured.
2. These data suggest that when the supplemental oxygen system is prescribed, the level of a patient's disability as well as the weight (and bulkiness) of the oxygen system should be considered. Since compliance to oxygen therapy is poor, perhaps a lighter system would improve the patient's acceptance of this therapy.
3. If breathlessness precludes walking a reasonable distance with either system (liquid or gaseous), then having an assistant carry the oxygen unit may be beneficial.

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Appendix 1

PATIENT PERCEIVED BREATHLESSNESS SCALE

Modified Borg Category Scale

0	Nothing at all
0.5	Very, very slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Very, very severe (almost maximal)
10	Maximal

Adopted from:
Burdon JG, Juniper EF, Killian KL: The perception of breathlessness in asthma. Am Rev Respir Dis 1982; 126: 825-8.

Appendix 2

PROTOCOL FOR FAMILIARIZATION SESSION

1. Inform patients of the purpose of the study:
   a) "Energy cost" to ambulate with two 0_2 systems.
   b) "Energy cost" to transport the liquid 0_2 system by two methods (cart, suspended from shoulder).
2. Sign Informed Consent Form.
3. Length of study: two weeks for pilot study, one week for main study.
4. Explain methodology - i.e. series of constant velocity 255m corridor walking tests performed at the Aberhart Centre (eight tests for pilot patients, four tests for main study patients) with two walking tests per day, with a 20 minute rest between walks, two days/week (Monday/Wednesday) at approximately the same time of day. Patients will be randomly assigned to transport either liquid or gaseous 0_2 using various carrying methods (for liquid). As well, there would be walking tests on a motorized treadmill, in the pulmonary function lab at the Walter Mackenzie Centre (four walks for pilot patients - two/day x two days, two walks for main study patients on same day with 20 minute rest

Appendix 2

between walks either carrying a liquid oxygen pack or no load for a duration of 10-12 minutes breathing through a mouthpiece.

5. Pulmonary function testing and ECG testing and assessment will precede the pilot and main study.
6. Explain parameters to be measured: HR, $Sa0_2$ and breathlessness (during corridor walking tests) with the addition of $\dot{V}0_2$ (during TM test).
7. Familiarize patients with the modified Borg Scale (a method to quantify breathlessness).
8. Provide an opportunity for patients to perform short practice corridor walking tests with the two oxygen systems and various liquid 0_2 transport methods.
9. Determine 0_2 flow rate to maintain $Sa0_2 \geq 90\%$.
10. Allow patients an opportunity to walk on the motorized treadmill.
11. Patients will be asked during the study to:
    a) maintain the same dosage and schedule of medications.
    b) maintain a regular diet.
    c) refrain from caffeine products two hours prior to testing.

Appendix 3

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Pulmonary Rehabilitation Assessment
Physical Therapy
SP. 8355 (0627.77)

Referring physician_____ Date _____

Patient Identification

Surname_____ First_____

Date of Birth _____ AHC#_____

Address_____ City_____ Postal Code_____

Telephone: Residence_____ Business_____

Patient History

Diagnosis_____ Date of most recent exam_____

Brief summary of recent pulmonary history_____

_____

Past Medical History

Cardiac disease

Describe_____

Neurological or musculoskeletal impairment affecting mobility?

Describe_____

Other_____

Family History

_____

_____

Current Medications

[] Yes [] No Nitrate preparations

[] Yes [] No Antihypertensives

[] Yes [] No Antiarrythmics

[] Yes [] No Oxygen

If yes,_____Litres/Minute

When used?_____

Appendix 3

[] Yes [] No Digoxin

[] Yes [] No Diurectics

[] Yes [] No Bronchodilators

Level of Activity

[] Sedentary [] 1 block [] 1-2 blocks [] 2-4 blocks [] > 4 blocks

Flights of stairs (10 stairs/flight): [] None [] < 1/2 [] 1/2
[] 1-2 [] > 2

Work: [] Retired [] Part-Time [] Full-Time

Laboratory Tests

PRTs: FEV1_____ FVC_____ FEV1/FVC_____ Other_____

Exercise test(s)_____

EKG_____

CXR_____

ABGs_____

Other_____

Physical Examination

Appearance_____

Cardiovascular: Pulse_____ BP_____ Heart sounds_____
Murmurs_____

Pulmonary_____

Musculoskeletal_____

Oxygen saturation test_____

Timed walk test_____

Functional assessment_____

Problems Identified

_____

_____

Appendix 3

Plan

Appendix 4

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Aberhart Centre
11402 University Avenue
Edmonton, Alberta
T6G 2J3

INFORMATION/CONSENT FORM

EFFICIENCY OF TRANSPORTING OXYGEN DELIVERY SYSTEMS:
METHODS TO IMPROVE THIS IN PATIENTS WITH COPD

Purpose of This Experiment

Supplemental oxygen for use outside the home is provided by two systems: compressed gas and liquid oxygen. The compressed gas comes in standard "E" cylinders made of cast iron and is wheeled on a cart. Liquid oxygen is stored in an oxygen pack and can be carried suspended from a strap or wheeled in a cart.

We would like to know if there is a difference in the amount of work done when walking with either oxygen system. Further, is one method of transporting the liquid oxygen (by the shoulder or cart) less energy demanding than the other.

You will be required to do standard lung function testing prior to the study and during the course of the investigation. Also, you will perform a series of supervised walks in a corridor and on a treadmill at a self-selected comfortable pace with the two oxygen systems and various carrying methods.

Corridor Walks

Prior to performing four corridor walking tests, you will practice walking with both oxygen systems and carrying methods. You will also walk on a treadmill with which you may or may not be familiar.

Two 300m walks (about one city block per walk) will be performed each day on two separate occasions, either pulling the oxygen on a wheeled cart, or carrying the pack of liquid oxygen over the shoulder. You will probably become moderately short of breath and be fatigued during the tests, but there will be ample time for recovery between walking tests.

Treadmill Walks

While breathing through a mouthpiece, you will perform two walking tests (10-12 minutes duration) at a comfortable pace either carrying an oxygen pack or not carrying the pack. Some skill is involved in walking on the treadmill which will be acquired during the familiarization session.

Some patients will be asked to volunteer to participate in a pilot study which will precede the main investigation. If you volunteer for the pilot study you will perform two walking tests per session for six sessions over a 2 week period.

Appendix 4

The total time commitment for participating in the main study will be approximately 6 hours (3 sessions on separate days and 2 hours per session). If you are involved in the pilot study, in addition to the main study, an additional 12 hours will be required.

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T6G 2J3

Consent

I acknowledge that the research procedures described on the Information Sheet above (Pulmonary Function Testing and Walking Tests) and of which I have a copy have been explained to me, and that any questions that I have asked have been answered to my satisfaction. In addition, I know that I may contact the person named below, if I have further questions either now or in the future. I understand that participation in this study is voluntary. I understand the possible risks of joining this research study. I have been assured that personal records relating to this study will be kept confidential. I understand that I am free to withdraw from the study at any time and that this will not affect my continuing medical care. I further understand that if the study is not undertaken, or if it is discontinued at any time, the quality of my medical care will not be affected. I understand that if any knowledge gained from the study becomes available that could influence my decision to continue in this study, I will be promptly informed.

_____
Name

The person who may be contacted about the research is:

Jim Brohman
Telephone: 492-6682 (work)
438-0939 (home)

_____
Date

Dr. N.E. Brown 492-6048

_____
Signature of Subject

_____
Signature of Witness

_____
Signature of Investigator

Appendix 5

PROTOCOL FOR CORRIDOR WALKING TESTS

1. Two patients per session will perform the walking tests on an individual basis.
2. Patients will have the HR transmitters applied to the chest wall; the HR monitor will be strapped to the assistant's wrist. HR will be recorded at 30 second intervals.
3. Patients will be randomly assigned to perform two 255m corridor walking tests at a comfortable pace and at a constant velocity with a 20 minute rest between tests per study day. The two oxygen systems and carrying methods are as follows:
   a) LOS - 2WC
   b) LOS - SHLD
   c) CGOS - 2WC
   d) Assistant-carried
4. Prior to walking with the CGOS, the flow rate will be checked with a calibrated flow meter (Erie™) to ensure the oxygen flow rate is the same as during walks on liquid oxygen.
5. The $Sa0_2$ will be measured by a Nonin pulse oximeter and recorded by a Nonin printer at 30 second intervals ($Sa0_2$ to be maintained at $\geq$ 90% during tests). The

Appendix 5

patient's designated finger will be used throughout testing to record $Sa0_2$ for all the walking tests).

6. Patients' rating of perceived dyspnea (Borg scale 0-10) will be recorded at rest and at one minute intervals. The "maximal" end of the scale will be anchored by having the patient recall the most severe dyspnea experienced in the past whereas the lower end of the scale will be described as the respiratory sensation while completely at rest.

7. Standard instructions for the Borg Scale will be read to the patient by the same tester prior to each exercise test. The instructions are as follows:

> "The Borg Scale is an indicator of the severity of your breathlessness. The scale ranges from 1 to 10 where a value of 0 represents nothing at all or no discomfort with your breathing and a score of 10 means that the intensity of the breathlessness is maximal. Imagine a situation or past experience which has caused the worst breathlessness for you - an equivalent sensation should represent a "10" on this scale. You will be asked every minute of the exercise test to verbalize a Borg rating between "0" and "10" which should represent your perceived level of breathlessness at that moment."

8. Prior to the test baseline HR, $Sa0_2$ and breathlessness values will be recorded.

Appendix 5

9. The tester will accompany the patients during the corridor walking tests (two per day) and record elapsed time every 85 m and breathlessness scores at one minute intervals. Following the walking test $Sa0_2$ and HR values will be downloaded from the oximeter and HR monitor respectively, and recorded at 30 seconds intervals on a data sheet.
10. Tests will be performed in an enclosed hospital corridor 85 m in length with a 20 minute rest between walks.
11. During the second walking test, patients will be given prompts by the tester (if need be) at 85 meter intervals to adjust their walking velocity so as to coincide with the velocity of the first walking test.
12. Pilot study patients will perform eight corridor walking tests (two walks/session, two days/week x two weeks) and the main study patients will perform four corridor walking tests (two tests/day x two days).
13. Patients will start each walking test with the liquid oxygen pack full and the gas cylinder full weight.
14. Patients will use the same side when pulling the LOS and CGOS on the two wheeled carts.

Appendix 5

15. The patients will be asked not to speak during the walking tests (except to report breathlessness scores).
16. The assistant will only speak when:
    (1) asking the patient their level of breathlessness (at one minute intervals).
    (2) giving prompts at 85 m intervals (if need be) to speed up or slow down to maintain constant velocity.

Appendix 6

EFFICIENCY OF TRANSPORTING OXYGEN DELIVERY SYSTEMS

Patient Name: _____ Date: _____

TIME	DISTANCE (METERS)				SaO2 (%)				Heart Rate (BPM)				RPD (0 - 10)				OXYGEN CONSUMPTION PREDICTED			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
@ REST																				
00:15																				
00:30																				
00:45																				
01:00																				
01:15																				
01:30																				
01:45																				
02:00																				
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05:15																				
05:30																				
05:45																				
06:00																				
06:15																				
06:30																				
06:45																				
07:00																				

1 = PORTABLE LIQUID OXYGEN SYSTEM - SHOULDER CART

2 = COMPRESSED GASEOUS OXYGEN SYSTEM ASSISTANT CARRIED

3 = PORTABLE LIQUID OXYGEN SYSTEM -

4 = PORTABLE LIQUID OXYGEN SYSTEM -

Appendix 7

PROTOCOL FOR TREADMILL TEST

1. The patients will be connected to a metabolic cart and breathe through a mouthpiece/valve system at a constant FIO_2 equivalent to the FIO_2 delivered by the LOS and CGOS used during the CWTS (see Table 5).
2. $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and tidal volume (VT) will be calculated on-line with a Sensor-Medics Horizon System™.
3. Results of these variables will be averaged over the last 30 seconds of each minute.
4. The patients will rest at least 10 minutes (sitting down) prior to the test.
5. Following the 10 minute rest, they will stand on the treadmill (TM) deck and breathe through the mouthpiece-valve system for four minutes prior to walking. At this time gas collection will occur, FIO_2 will be measured, and $\dot{V}O_2$, $\dot{V}CO_2$, $\dot{V}E$ and VT will be measured.
6. The $Sa0_2$ will be measured by a pulse oximeter (Ohmeda 8640D).
7. HR will be recorded continuously on an ECG recorder (Hewlett-Packard 4700™).
8. Breathlessness will be measured by a modified Borg

Appendix 7

Scale. Patients will point to the number which best describes their intensity of breathlessness (scale 0-10) at the moment (measurements done at one minute intervals).

9. Patients will be randomly assigned to either carry the liquid 0_2 pack suspended from one shoulder or to walk on the track with no load.
10. TM speed will start at 1 mph and will increase by .5 mph at two minute intervals up to a maximum of 2.5 mph. Once this speed is achieved, if maximum HR values are still below those attained during corridor walks, treadmill grade will initially be 0 and then be increased by 2% per 2 minutes to a maximum grade of 10%.
11. Patients will rest 20 minutes between the two walking tests.
12. Pilot study patients will perform four walking tests (two walks/test day) and main study patients will perform two walking tests (same day).

Appendix 8

EFFICIENCY OF TRANSPORTING OXYGEN DELIVERY SYSTEMS

PATIENT'S NAME:_____ DATE:_____

TREADMILL

WALK "A"			WALK "B"			
TIME	HR	SaO_2	RPD	HR	SaO_2	RPD
00:30						
01:00						
01:30						
02:00						
02:30						
03:00						
03:30						
04:00						
04:30						
05:00						
05:30						
06:00						
06:30						
07:00						
07:30						
08:00						
08:30						
09:00						
09:30						
10:00						
10:30						
11:00						
11:30						
12:00						
12:30						
13:00						

Appendix 9

Derivation of $\dot{V}O_2$ Calculated Values

- treadmill exercise performed while carrying the liquid oxygen pack
- HR and $\dot{V}O_2$ measured at 30 second intervals
- transport methods:

  1 = gaseous "E" cylinder pulled on a cart

  2 = liquid oxygen pack carried from shoulder

  3 = liquid oxygen pack pulled on cart

  4 = assistant-carried

Patient 1 (JM)

1. Treadmill Exercise

HR	107	109	113	115	115	116	117	118	119	122	122	124	125	128
$\dot{V}O_2$	5.3	5.8	6.6	7.5	9	10.1	10.9	11.1	11.9	13.1	13.9	14	14.6	14.2

Regression Equation:

$Y = .52X - 51.2 \qquad r^2 = .92$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
123.5	118	124	112.5

Appendix 9

3. $\dot{V}O_2$ (calculated) Values by substituting mean HR (from #2) into regression equations:

13.0	10.2	13.3	7.3

Patient 2 (TG)

1. Treadmill Exercise

HR	84	83	84	85	88	89	91	91	94	94	94	95	100	97
$\dot{V}O_2$	8.9	9.2	9.8	9.8	10.6	10.9	11.3	11.4	11.8	12.5	11.8	11.9	12.6	12.9

Regression Equation:

$Y = 0.23X - 9.84 \quad r^2 = .92$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
88.5	90.5	90.5	88.5

3. $\dot{V}O_2$ (predicted) values

10.5	11	11	10.5

Patient 3 (ML)

1. Treadmill Exercise

HR	110	106	106	108	109	108	109	110	110	112	113	112	113	114	115
$\dot{V}O_2$	8	8.4	8.2	8.8	8.8	8.9	9	9.7	9.7	9.9	10.4	10.9	11.1	11.2	11.6

Regression Equation:

$Y = 0.38X - 32.61 \quad r^2 = .81$

Appendix 9

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
122.5	122	119	113.5

3. $\dot{V}O_2$ (calculated) values

13.9	13.8	12.6	10.5

Patient 4 (MU)

1. Treadmill Exercise

HR	119	120	118	121	121	121	122	124	124	126	129	126
$\dot{V}O_2$	8.5	9.3	8.7	9.9	10.3	10	10.6	11.3	12.1	12.8	13.9	14.9

Regression Equation:

$Y = 0.59X - 60.93 \qquad r^2 = .89$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
116	119	112.5	113.5

3. $\dot{V}O_2$ (calculated) values:

7.5	9.3	5.4	6

Patient 5 (GP)

1. Treadmill Exercise

HR	117	123	125	127	130	131	133	136	137	138

Appendix 9

$\dot{V}0_2$	6.1	6.4	8.6	10.4	11.3	11.6	12	12.1	12.4	12.4

Regression Equation:

$Y = 0.34X - 33.60 \qquad r^2 = .88$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
121	118	123.5	117.5

3. $\dot{V}0_2$ (calculated) values:

7.5	6.5	8.4	6.4

Patient 6 (PM)

1. Treadmill Exercise

HR	91	93	93	95	97	98	100	100	96	105	105	108	110	111
$\dot{V}O_2$	9.2	10	11.1	11.5	13.1	13	13.4	14.4	14.4	14	14.6	15.2	15.4	15.8

Regression Equation:

$Y = 0.27X - 14.13 \quad r^2 = 0.77$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method			
1	2	3	4
109.5	103	106.5	100.5

Appendix 9

3. $\dot{V}O_2$ (calculated) values

15.4	13.7	14.6	13

Patient 7 (JAM)

1. Treadmill Exercise

HR	90	99	96	99	102	103	106	109	111	112	114	115
$\dot{V}O_2$	4.6	4.9	6.4	8.1	9.2	10.3	10.9	11.3	11.6	11.6	12.2	12.5

Regression Equation:

$$Y = 0.34X - 25.82 \quad r^2 = 0.87$$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method

1	2	3	4
115.5	111	108.5	108.5

3. $\dot{V}O_2$ (calculated) values

13.5	11.9	11.1	11.1

Patient 8 (SC)

1. Treadmill Exercise

HR	103	109	111	121	131	136	141

Appendix 9

$\dot{V}O_2$ 6.1 7.9 9.8 12.7 14.8 17.7 18.8

Regression Equation:

$Y = 0.33X - 27.50 \quad r^2 = 0.99$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method

1	2	3	4
109	106.5	104	106

3. $\dot{V}O_2$ (calculated) values

8.5	7.6	6.8	7.5

Patient 9 (SM)

1. Treadmill Exercise

HR 85 85 86 88 88 88 90 91 91 93 93 99 99 101 101

$\dot{V}O_2$ 9.6 9.4 8.7 9.8 10.1 10.4 10.1 11.2 11.8 12.1 12.4 13.3 13.2 13.5 13.2

Regression Equation:

$Y = 0.27X - 13.91 \quad r^2 = .90$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method

Appendix 9

1	2	3	4
96.5	91	88	84.5

3. $\dot{V}O_2$ (calculated) values

12.1	10.7	9.9	8.9

Patient 12 (KH)

1. Treadmill Exercise

HR	78	81	84	87	91	96	97	94	96	96	96	96
$\dot{V}O_2$	7.1	7.5	8.7	8.9	9.3	11.1	11.2	11.7	12.1	11.6	12.2	11.7

Regression Equation:

$$Y = 0.26X - 13.58 \qquad r^2 = 0.92$$

2. Mean HR values (last 30 seconds) during corridor walking tests

Transport Method

1	2	3	4
91.5	95	88	88

3. $\dot{V}O_2$ (calculated) values by substituting mean HR (from 2) into regression equation:

10.2	11.1	9.3	9.3

Appendix 10

PATIENT SURVEY - OXYGEN STUDY

1. If you perceived a difference in:

   A) the ease of pulling the two oxygen systems on a cart, then circle the letter of the system which required the least energy. If no difference was perceived, the do not circle a letter.

      a) The compressed gaseous oxygen cylinder.

      b) The liquid oxygen pack.

   B) carrying the liquid oxygen pack suspended from your shoulder versus pulling the pack behind on a cart, then circle the letter of the transport method which required the least energy. If no difference was perceived, then do not circle a letter.

      a) By shoulder.

      b) By two-wheeled cart.

   C) the energy demand of carrying/pulling the two oxygen systems by the various transport methods, then rank the systems/ methods (easiest to most difficult) by writing a number from 1 to 4 beside the choices below. If no difference was perceived between the oxygen systems and transport methods, then do not rank the choices.

      i.e. Number 1 indicates the easiest, number 4 the most difficult.

      a) The compressed gaseous oxygen cylinder pulled on a 2-wheeled cart.

      b) The liquid oxygen pack carried suspended from the shoulder.

      c) The oxygen supply carried by an assistant.

Appendix 10

d) The liquid oxygen pack pulled on a 2-wheeled cart.

D) the energy demand of walking on the treadmill with or without an added load (oxygen pack), then circle the letter of the condition which required the <u>least</u> energy. If no difference was perceived, then <u>do not</u> circle a letter.

a) Carrying oxygen pack.

b) No load.

2. If you had a preference between the two oxygen systems (liquid or gas), then circle the letter of the system which you would prefer to use on outings.

a) The compressed gas cylinders.
b) The liquid oxygen packs.

3. Why do you prefer this system?

Appendix 11

Sample size calculations for treatment studies
1. Interval/ordinal dependent variable

$$n/group = 2\sigma^2/(\mu_2 - \mu_1)^2 \times f(\alpha, ß)^1$$

where σ = standard deviation for μ^1

μ_1 = mean response on standard therapy
} smallest difference if more th
μ_2 = mean response on comparison therapy

[1] Values of $f(\alpha, ß)$ to be used in formula for required number of patients

		ß (type II error)			
		0.05	0.1	0.2	0.5
	0.1	10.8	8.6	6.2	2.7
α (type 1	0.05	13.0	10.5	7.9	3.8
error)	0.02	15.8	13.0	10.0	5.4
	0.01	17.8	14.9	11.7	6.6

Adapted from Pocock S: Clinical Trends. Chichester, England: John Wiley and Sons, 1983.

Appendix 11

Derivation of sample size needed to show a significant difference in the variables of interest. Calculations based on

a) α level of 0.05
b) ß level of 0.2
c) mean differences between dependent variables from Table 8
d) formula and table from Pocock (see Appendix 11, p.98).

1. CGOS vs. LOS-2WC

a) heart rate

$$n = \frac{2(12.3)^2}{(106.5 - 109.4)^2} \quad x\ 7.9 = 284$$

b) oxygen uptake

$$n = \frac{2(2.7)^2}{(10.2 - 11.0)^2} \quad x\ 7.9 = 180$$

c) breathlessness

$$n = \frac{2(0.8)^2}{(2.6 - 3.2)^2} \quad x\ 7.9 = 28$$

TABLE 1: Anthropometric and Pulmonary Function Values of Patients Studied

Patient	Age (yrs)	Ht. (cm)	Wt. (kg)	FVC (L)	FEV_1 (L)	FEV_1/ FVC (%)	TLC (L)	TLC (% pred)	RV (L)	RV (% pred)	FRC (L)	FRC (% pred)	DLCO/VA L/min/mmHg	DLCO/VA (% pred)
1. JM	70	175	82	3.11	0.85	27	8.40	132	4.49	232	6.16	233	2.46	61
2. TG	62	175	72	2.96	0.95	43	6.07	95	3.11	169	4.07	154	2.38	56
3. ML	70	176	71	3.34	1.08	32	8.69	137	4.45	229	5.87	222	0.58	15
4. MU	58	181	122	2.46	1.27	52	6.17	91	3.33	176	4.09	145	3.99	93
5. GP	80	155	73	2.15	0.82	38	4.40	92	2.25	135	2.81	140	2.82	68
6. PM	74	171	81	3.80	1.38	36	6.59	110	2.79	147	4.81	193	2.78	70
7. JAM	69	167	89	2.29	0.81	35	5.98	104	2.83	158	3.72	155	2.04	49
8. SC	73	173	77	2.84	0.94	33	7.03	118	3.99	212	5.06	203	2.90	72
9. SM	68	179	80	2.35	0.55	23	7.56	115	4.93	251	6.19	227	1.75	43
10. KH	64	162	80	1.79	0.84	47	4.97	93	3.04	186	3.47	155	3.44	77
MEAN	68.8	171.4	82.7	2.71	0.95	36.6	6.59	108.7	.52	189.5	4.63	182.7	2.51	60.4
S.D.	6.3	8.0	14.8	0.61	0.24	8.8	1.38	16.7	0.89	39.5	1.12	36.8	0.94	21.4

Definition of abbreviations: FVC = Forced Vital Capacity; FEV_1 = Forced Expiratory Volume in 1 second; TLC = Total Lung Capacity; RV = Residual Volume; FRC = Functional Residual Capacity; DLCO/VA = Diffusion Capacity for Carbon Monoxide/Alveolar Volume. TLC, RV and FRC values were obtained using the helium-dilution method.

TABLE 2: Portable Oxygen Delivery Systems and Transport Methods Utilized When Ambulating in a Corridor

Oxygen System	Transport Method		
LOS	AC	2WC	SH
CGOS		2WC	

Definition of abbreviations: LOS = Liquid Oxygen System; CGOS = Compressed Gaseous Oxygen System; AC = Assistant Carried; 2WC = 2-Wheeled Cart; SH = Shoulder

TABLE 3: Protocol For Repeat Testing of Pilot Patients (n=4) During Corridor and Treadmill Walking Tests

			Week 1		Week 2	
Session #	Types of Exercise	Walk #	O_2 System	Transport Method	O_2 System	Transport Method
1	CWT	1	LOS	SH	LOS	SH
		2	CGOS	2WC	CGOS	2WC
2	CWT	1	LOS	AC	LOS	AC
		2	LOS	2WC	LOS	2WC
3	TWT	1	gaseous	L	gaseous	L
		2	gaseous	NL	gaseous	NL

Definition of abbreviations: O_2 = Oxygen; CWT = Corridor Walking Test; TWT = Treadmill Walking Test; L = Load (liquid oxygen pack full of oxygen) suspended from the shoulder; NL = No Load

TABLE 4: The Weight of Portable Oxygen Delivery Systems and Transport Carts

System	Weight (kg)
Liquid Oxygen	
Cryogenics Stroller™	4.3
Cryogenics two-wheeled cart	2.3
Total	6.6
Compressed Gaseous	
"E" cylinder	6.6
Chemtron™ regulator & flowmeter	1.4
VariFlow™ two-wheeled cart	2.6
Total	10.6

TABLE 5: Conversion of Supplemental Oxygen Liter Flow (By Nasal Cannula) to Approximate Fractional Oxygen Concentration

Oxygen System	Oxygen Flow Rate (L/min)	Approximate FIO_2
Gaseous or Liquid	1	0.24
	2	0.28
	3	0.32
	4	0.36
	5	0.40
	6	0.44

Assumptions: normal tidal volume = 500ml and respiratory rate = 20 breaths/min.
Adapted from Lough MD, Chatburn RL, Schrock WA: Handbook of Respiratory Care. Chicago: Year Book Medical Publishers, 1990; 141.

TABLE 6: A Comparison of Heart Rate Measurements Recorded Simultaneously With A Sport Tester™ and ECG On One Patient During Two Exercise Tests on a Treadmill

Time (minutes)	Load		No Load	
	Sport tester	ECG	Sport tester	ECG
0	82	82	84	84
0.5	83	85	79	80
1	83	82	82	81
1.5	89	89	83	84
2.0	91	87	81	87
2.5	96	95	89	89
3.0	93	93	91	89
3.5	99	97	89	96
4.0	99	98	92	92
4.5	102	101	92	91
5.0	102	106	95	95
5.5	107	106	99	100
6.0	109	108	99	101
6.5	114	108	101	102
7.0	112	106	105	101
7.5	103	102	99	99
Mean	97.8	96.6	91.3	91.9
(SD)	(9.9)	(9.3)	(7.7)	(7.2)

$p > 0.05$ vs ECG (load and no load)
$r = 0.97$ sport tester vs. ECG (load)
$r = 0.94$ sport tester vs. ECG (no load)

TABLE 7: Summary Data of Corridor Walking Tests by the four Pilot Patients Performed on Two Occasions

Variable	Oxygen Systems and Transport Methods							
	CGOS		LOSSH		LOS-2WC		AC	
	Session		Session		Session		Session	
	1	2	1	2	1	2	1	2
Heart Rate (BPM)								
Mean	103.1	103.6	100.9	106.8	97.1	102.4	96.8	102.0
(SD)	(11.1)	(16.6)	(13.1)	(14.7)	(10.7)	(13.3)	(12.3)	(17.9)
r	0.93		0.68		0.98		0.84	
Calculated Oxygen Uptake (ml/kg/min)								
Mean	11.1	11.4	10.3	12.2	9.3	11.2	9.2	11.0
(SD)	(2.2)	(2.1)	(1.9)	(1.2)	(1.8)	(1.6)	(1.5)	(1.9)
r	0.32		0.65		0.84		0.09	
Arterial Oxygen Saturation (%)								
Mean	88.9	88.0	89.9	88.0	90.8	89.4	90.6	90.0
(SD)	(1.31)	(5.8)	(2.3)	(2.2)	(1.3)	(1.6)	(2.9)	(1.7)
r	0.70		0.10		0.28		0.96	
Rating of Perceived Dyspnea (slight to moderate)								
Mean	3.3	3.6	2.6	3.6	2.7	2.9	2.2	2.8
(SD)	(0.64)	(0.48)	(1.1)	(1.7)	(0.75)	(0.25)	(1.1)	(0.38)
r	0.89		0.24		0.08		0.009	

Definition: r = correlation coefficient from regression equations
note: regressions were obtained from comparing the measurements done at the same time during each of the two corridor walks.

TABLE 8: Comparison of the Physiologic and Perceptual Responses During Corridor Walking Tests Using Two Oxygen Systems and Three Transport Methods

Variable	Oxygen Systems and Transport Methods Controls			
	CGOS	LOSSH	LOS-2WC	AC
Heart Rate (beats/min)				
Mean	109.4*	107.4*	106.5	103.3
(SD)	(12.3)	(11.2)	(12.8)	(10.8)
Oxygen Uptake (calculated) (ml/Kg/min)				
Mean	11.0*	10.6*	10.2	9.1
(SD)	(2.7)	(2.2)	(2.7)	(2.1)
Arterial Oxygen Saturation (%)				
Mean	88.7	89.9	90.3	90.3
(SD)	(3.9)	(3.7)	(3.1)	(3.2)
Rating of Perceived Dyspnea				
Mean	3.2+	2.9+	2.6	2.3
(SD)	(0.8)	(0.10)	(0.8)	(0.9)

Data as expressed as mean $\pm$ SD

* $p<.05$ = significantly greater than the AC method

\+ $p<.05$ = significantly less than the AC method

Note: Oxygen uptake obtained from HR data using the regression for HR vs. $\dot{V}O_2$ obtained during the treadmill tests.

TABLE 9: Arterial Oxygen Saturation (%) During the Last 30 Seconds of the Corridor Walking Tests

Patient	Oxygen Tranport Method 1	2	3	4	Oxygen Flow Rate (L/min.)
1. JM	86.5	89.5	88.0	88.5	5
2. TE	83.0	83.0	86.0	84.5	3
3. ML	83.0	86.5	88.0	90.0	4
4. MU	90.5	92.0	91.5	91.0	3
5. GP	94.0	94.0	92.5	94.0	2
6. PM	94.0	94.0	94.0	92.5	3
7. JAM	88.0	91.0	91.0	92.0	3
8. SC	87.5	86.5	89.5	86.5	3
9. SM	90.0	91.0	92.5	93.0	5
10. KH	90.0	91.0	90.0	91.0	2
Mean	88.7	89.9	90.3	90.3	3.3
(SD)	(3.7)	(3.4)	(2.3)	(2.8)	(1.1)

TABLE 10: Comparison of Patients' Arterial Oxygen Saturation During the Last 30 Seconds of the Corridor Walking Tests and the Treadmill Tests

Patient	SaO_2 (%)	
	Corridor Tests	Treadmill Tests
1	88.1	95.9
2	84.1	94.2
3	86.9	97.0
4	91.3	97.1
5	93.6	96.8
6	93.6	93.0
7	90.5	92.9
8	87.5	93.6
9	91.6	94.6
10	90.5	94.6
Mean	89.8	95.0
(SD)	(3.5)	(1.5)

$p<0.05$ SaO_2 (corridor tests vs. treadmill tests)

Note:

Each SaO_2 value above (under the corridor tests) is the mean of the SaO_2 values (during the last 30 seconds of exercise) for oxygen transport methods one to four (see Table 9).

Each SaO_2 value above (under the treadmill tests) is the mean of the SaO_2 values (during the last 30 seconds of exercise) while walking with and without an oxygen pack.

TABLE 11: Analysis of Variance of the Variables of Interest During the Corridor Walking Tests Using the Two Oxygen Systems and Three Transport Methods

Dependent Variable	Statistical Method	F-Ratio	Significance of F	Power at 0.05 Level
Heart Rate	Greenhouse-Geisser	8.45	0.001*	0.98
Oxygen Uptake (calculated)	Greenhouse-Geisser	6.40	0.008*	0.94
Arterial Oxygen Saturation	Greenhouse-Geisser	3.63	0.048	0.73
Rating of Perceived Dyspnea	Greenhouse-Geisser	9.06	0.001*	0.99

Definition of abbreviations: F-ratio = mean square error among groups/mean square error within groups

* $p<0.01$

TABLE 12: Post Hoc Comparisons For The Variables of Interest Following the Corridor Walking Tests

	Transport Method					
Variable	CGOS vs LOSSH	CGOS vs LOSC	CGOS vs AC	LOSSH vs LOS-2WC	LOS-SHLD vs AC	CGOS vs LOSSH
Heart Rate						
F	2.72	6.39	22.00	0.42	20.75	5.71
sig. of F	0.133	0.032	0.001*	0.531	0.001*	0.041
Oxygen uptake						
F	2.05	6.63	17.19	0.30	14.37	3.65
sig. of F	0.186	0.030	0.002*	0.597	0.004*	0.088
Arterial Oxygen Saturation						
F	6.14	7.77	4.26	0.69	0.84	0.00
sig. of F	0.035	0.021	0.069	0.426	0.384	1.00
Rating of Perceived Dyspnea						
F	1.79	9.70	28.13	2.05	18.45	3.84
sig. of F	0.214	0.012	0.000*	1.86	0.002*	0.082

* = significant (sig.) $p < 0.008$ (0.05 / 6)

TABLE 13: A Comparison of Oxygen Uptake, Carbon Dioxide Production, and Breathlessness During the Last 30 Seconds of the Treadmill Exercise Tests Walking With and Without a Liquid Oxygen Pack

Patient	$\dot{V}O_2$ (ml/kg/min.) Load	No Load	$\frac{\text{Load - No Load}}{\text{Load}} \times 100$ (%)	$\dot{V}CO_2$ (ml/kg/min.) Load	No Load	Load/No Load (%)	Breathlessness Load	No Load
1. JM	14.5	14.6	- 0.68	10.8	11.7	- 7.7	5.3	3.7
2. TG	12.8	13.0	- 1.5	9.4	9.6	- 2.1	3.0	3.0
3. ML	11.4	10.2	+ 11.8	9.7	8.5	+ 14.1	4.5	4.0
4. MU	14.4	11.3	+ 27.4	10.9	8.4	+ 29.8	5.5	4.0
5. GP	12.4	11.8	+ 5.1	10.2	9.4	+ 8.5	1.0	2.0
6. PM	15.6	13.1	+ 19.1	14.1	10.6	+ 33.0	3.5	2.5
7. JAM	12.4	11.3	+ 9.7	9.9	9.2	+ 7.6	4.5	3.5
8. SC	13.6	12.1	+ 12.4	12.3	9.9	+ 24.2	3.5	3.3
9. SM	13.4	12.1	+ 10.7	10.6	10.0	+ 6.0	4.5	7.0
10. KH	12.0	11.6	+ 3.4	9.6	9.3	+ 3.2	3.0	3.0
Mean	13.3	12.1	+ 9.7	10.8	9.7	+ 11.7	3.8	3.6
(SD)	(1.4)	(1.2)	(10.1)	(1.4)	(0.9)	(12.8)	(1.3)	(1.3)

* $p < 0.05$ vs. no load

TABLE 14: The Relationship Between Heart Rate and Oxygen Consumption During The Treadmill Walking Tests

Subject	HR - $\dot{V}O_2$ r^2	Regression Equation
1 (JM)	0.92	$\dot{V}O_2 = 0.52X - 51.2$
2 (TG)	0.92	$\dot{V}O_2 = 0.23X - 9.84$
3 (ML)	0.81	$\dot{V}O_2 = 0.38X - 32.61$
4 (MU)	0.89	$\dot{V}O_2 = 0.59X - 60.93$
5 (GP)	0.88	$\dot{V}O_2 = 0.34X - 33.60$
6 (PM)	0.77	$\dot{V}O_2 = 0.27X - 14.13$
7 (JAM)	0.87	$\dot{V}O_2 = 0.34X - 25.82$
8 (SC)	0.99	$\dot{V}O_2 = 0.33X - 27.50$
9 (SM)	0.90	$\dot{V}O_2 = 0.27X - 13.91$
10 (KH)	0.92	$\dot{V}O_2 = 0.26X - 13.58$
Mean	0.89	
(SD)	(0.06)	

Definition of abbreviations: r^2 = coefficient of determination

TABLE 15: Comparison of the HR-$\dot{V}O_2$ Regression Equation Slopes For the Four Pilot Patients During Repeat Testing on the Treadmill

Patient	Slope	
	Time 1	Time 2
7. JAM	0.34	0.34
8. SC	0.33	0.46
9. SM	0.27	0.36
10. KH	0.26	0.33
Mean	0.30	0.37
(SD)	(0.04)	(0.06)

$p > 0.05$

TABLE 16: Initial and Final Pulmonary Function Test Results For All Patients

Patient	FEV_1(L) Initial	FEV_1(L) Final	FVC(L) Initial	FVC(L) Final
1. JM	0.85	0.81	3.11	3.12
2. TG	0.95	0.72	2.96	2.06
3. ML	1.08	0.83	3.34	3.49
4. MU	1.93	1.27	3.32	2.46
5. GP	0.95	0.82	2.2	2.15
6. PM	1.38	1.24	3.8	3.69
7. JAM	1.09	0.81	2.99	2.29
8. SC	0.94	0.54	2.84	2.2
9. SM	0.56	0.55	2.28	2.35
10. KH	0.84	0.75	1.79	1.66
Mean	1.06	0.83	2.87	2.55
(SD)	(0.35)	(0.23)	(0.58)	(0.63)

$p < 0.05$ for FEV_1 and FVC initial vs. final test

TABLE 17: Questionnaire Results Comparing The "Energy Demand" of Ambulating With Two Oxygen Systems by Three Transport Methods

Oxygen System and Transport Method	Rating	# of Patients	%
CGOS vs LOS - 2WC	+1	6/10	60
CGOS vs LOS - 2WC	0	4/10	40
LOSSH vs all other methods	+1	8/10	80
LOSSH vs all other methods	0	4/12	33
AC vs all other methods	-1	10/10	100

Definition of abbreviations: +1 = more energy demanding
0 = no perceived difference
-1 = less energy demanding

FIGURE 1: Comparison of Heart Rate Using the ECG Versus the Sport Tester While Carrying an Oxygen Pack For Patient #10.

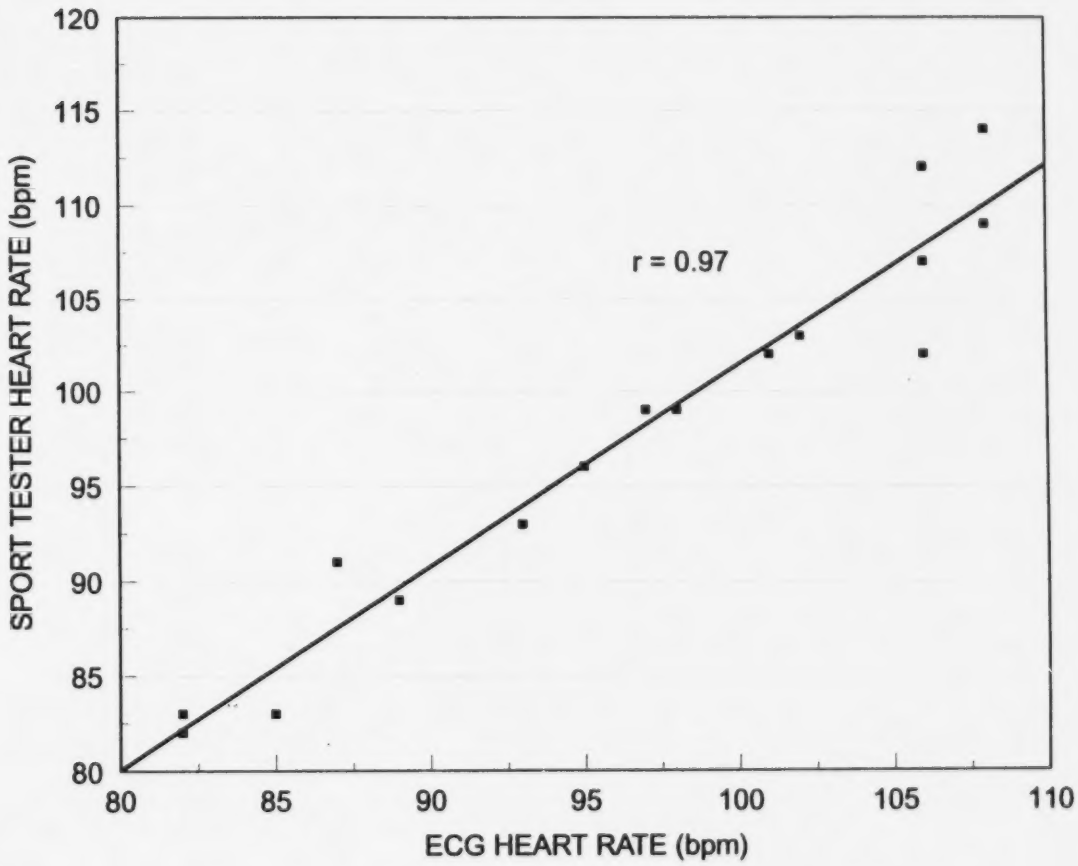

FIGURE 2: Comparison of Heart Rate Using The ECG Versus the Sport Tester Without Carrying an Oxygen Pack For Patient #10.

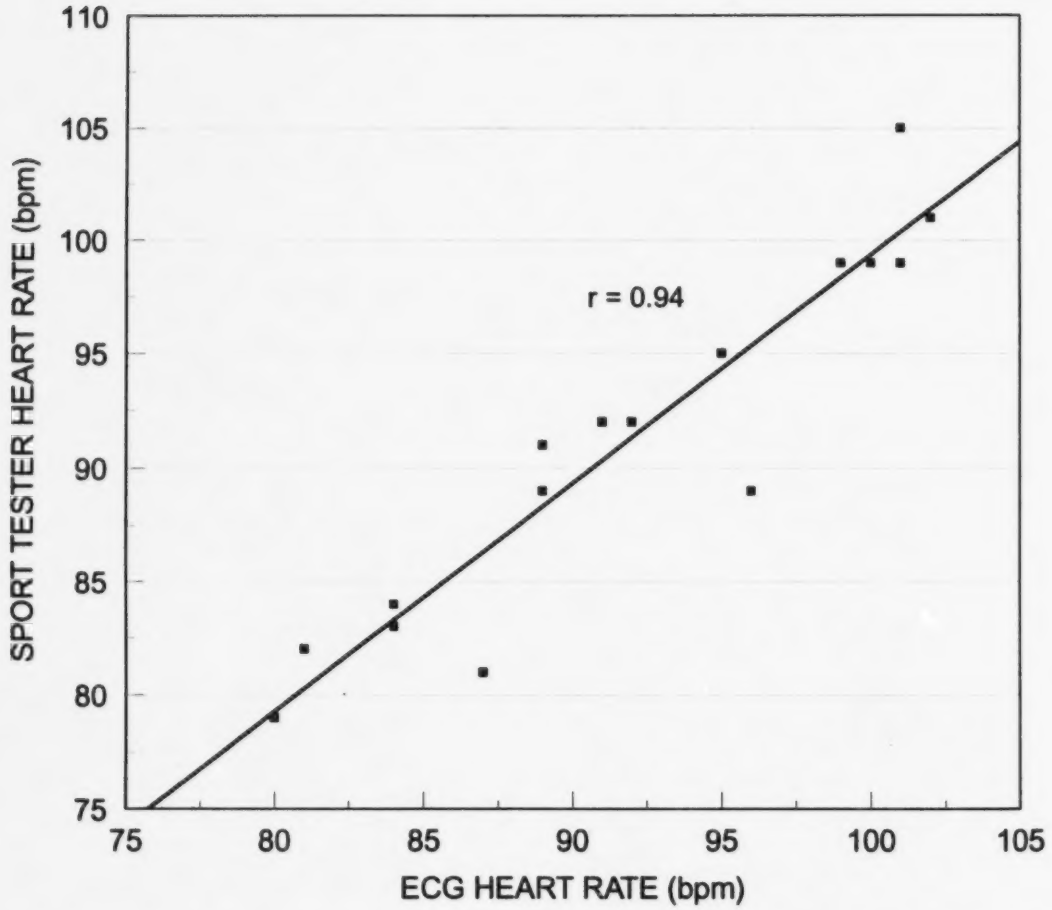

FIGURE 3: Mean Changes in Arterial Oxygen Saturation During Various Methods of Oxygen Transport With Two Oxygen Systems (see table 8 for SD).

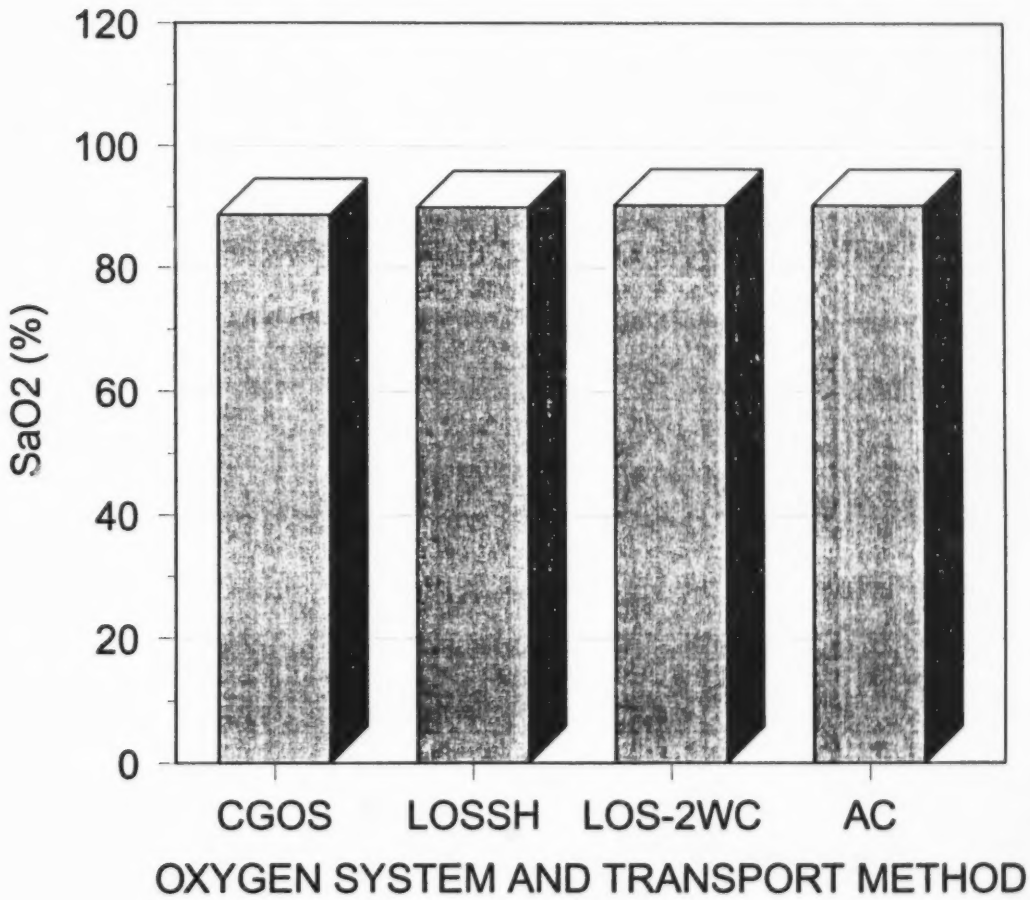

FIGURE 4: Mean Changes in Heart Rate During Different Methods of Oxygen Transport With Two Oxygen Systems (see table 8 for SD).

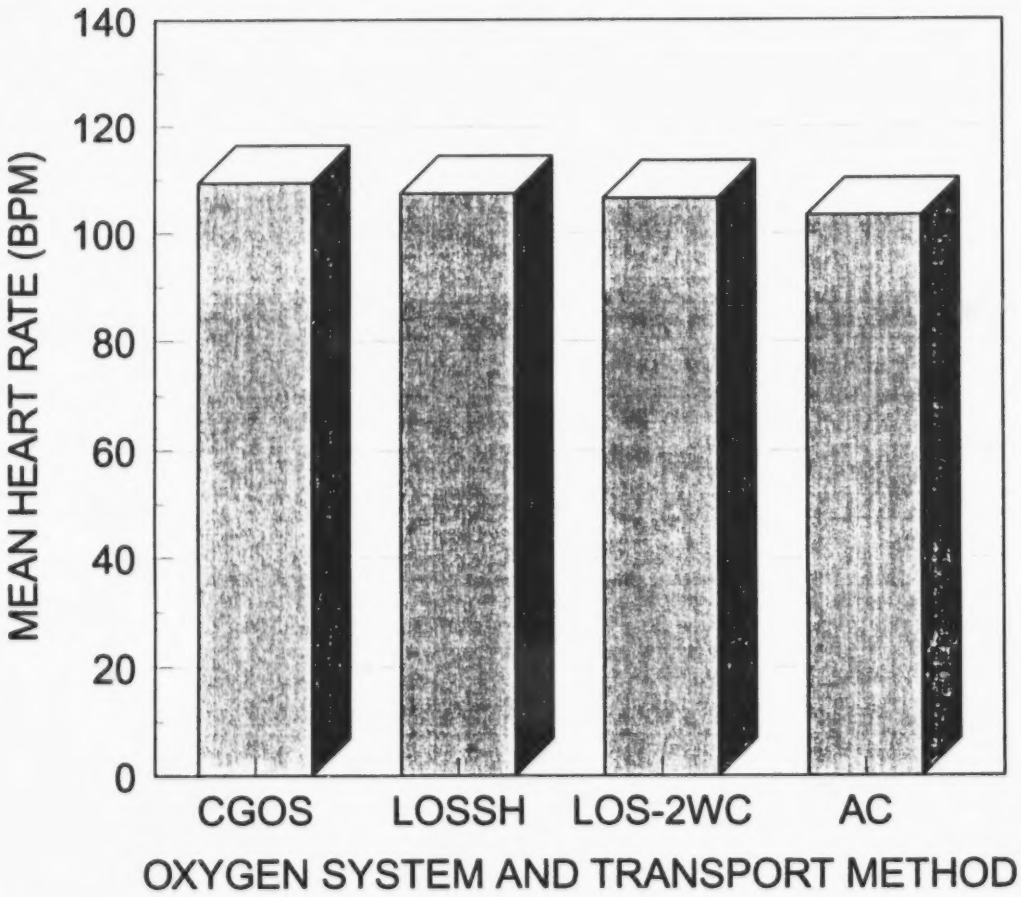

FIGURE 5: Mean Changes in Calculated Oxygen Uptake During Different Methods of Oxygen Transport (see table 8 for SD).